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LIBRO 1

Constitución del Estado Libre Asociado de Puerto Rico

Preámbulo

*N*osotros, el pueblo de Puerto Rico, a fin de organizarnos políticamente sobre una base plenamente democrática, promover el bienestar general y asegurar para nosotros y nuestra posteridad el goce cabal de los derechos humanos, puesta nuestra confianza en Dios Todopoderoso, ordenamos y establecemos esta Constitución para el Estado Libre Asociado que en el ejercicio de nuestro derecho natural ahora creamos dentro de nuestra unión con los Estados Unidos de América.

Al así hacerlo declaramos:

Que el sistema democrático es fundamental para la vida de la comunidad puertorriqueña;

Que entendemos por sistema democrático aquél donde la voluntad del pueblo es la fuente del poder público, donde el orden político está subordinado a los derechos del hombre y donde se asegura la libre participación del ciudadano en las decisiones colectivas;

Que consideramos factores determinantes en nuestra vida la ciudadanía de los Estados Unidos de América y la aspiración a continuamente enriquecer nuestro acervo democrático en el disfrute individual y colectivo de sus derechos y prerrogativas; la lealtad a los postulados de la Constitución Federal; la convivencia en Puerto Rico de las dos grandes culturas del hemisferio americano; el afán por la educación; la fe en la justicia; la devoción por la vida esforzada, laboriosa y pacífica; la fidelidad a los valores del ser humano por encima de posiciones sociales, diferencias raciales e intereses económicos; y la esperanza de un mundo mejor basado en estos principios.

ARTICULO I

DEL ESTADO LIBRE ASOCIADO

Sección 1. — Se constituye el Estado Libre Asociado de Puerto Rico. Su poder político emana del pueblo y se ejercerá con arreglo a su voluntad, dentro de los términos del convenio acordado entre el pueblo de Puerto Rico y los Estados Unidos de América.

Sección 2. — El gobierno del Estado Libre Asociado de Puerto Rico tendrá forma republicana y sus Poderes Legislativo, Ejecutivo y Judicial, según se establecen por esta Constitución, estarán igualmente subordinados a la soberanía del pueblo de Puerto Rico.

Sección 3. — La autoridad política del Estado Libre Asociado de Puerto Rico se extenderá a la Isla de Puerto Rico y a las islas adyacentes dentro de su jurisdicción.

Sección 4. — La sede de gobierno será la ciudad de San Juan Bautista de Puerto Rico.

ARTICULO II

CARTA DE DERECHOS

Sección 1. — La dignidad del ser humano es inviolable. Todos los hombres son iguales ante la ley. No podrá establecerse discrimen alguno por motivo de raza, color, sexo, nacimiento, origen o condición social, ni ideas políticas o religiosas. Tanto las leyes como el sistema de instrucción pública encarnarán estos principios de esencial igualdad humana.

Sección 2. — Las leyes garantizarán la expresión de la voluntad del pueblo mediante el sufragio universal, igual, directo y secreto, y protegerán al ciudadano contra toda coacción en el ejercicio de la prerrogativa electoral.

Sección 3. — No se aprobará ley alguna relativa al establecimiento de cualquier religión ni se prohibirá el libre ejercicio del culto religioso. Habrá completa separación de la iglesia y el estado.

Sección 4. — No se aprobará ley alguna que restrinja la libertad de palabra o de prensa o el derecho del pueblo a reunirse en asamblea pacífica y a pedir al gobierno la reparación de agravios.

Sección 5. — Toda persona tiene derecho a una educación que propenda al pleno desarrollo de su personalidad y al fortalecimiento del respeto de los derechos del hombre y de las libertades fundamentales. Habrá un sistema de instrucción pública el cual será libre y enteramente no sectario. La enseñanza será gratuita en la escuela primaria y secundaria y, hasta donde las facilidades del Estado lo permitan, se hará obligatorio para la escuela primaria. No se utilizará propiedad ni fondos públicos para el sostenimiento de escuelas o instituciones educativas que no sean las del Estado. Nada de lo contenido en esta disposición impedirá que el Estado pueda prestar a cualquier niño servicios no educativos establecidos por la ley para protección o bienestar de la niñez. La asistencia obligatoria a las escuelas públicas primarias, hasta donde las facilidades del Estado lo permitan, según se dispone en la presente, no se interpretará como aplicable a aquéllos que reciban instrucción primaria en escuelas establecidas bajo auspicios no gubernamentales.

Sección 6. — Las personas podrán asociarse y organizarse libremente para cualquier fin lícito, salvo en organizaciones militares o cuasi militares.

Sección 7. — Se reconoce como derecho fundamental del ser humano el derecho a la vida, a la libertad y al disfrute de la propiedad. No existirá la pena de muerte. Ninguna persona será privada de su libertad o propiedad sin debido proceso de ley, ni se negará a persona alguna en Puerto Rico la igual protección de las leyes. No se aprobarán leyes que menoscaben las obligaciones contractuales. Las leyes determinarán un mínimo de propiedad y pertenencias no sujetas a embargo.

Sección 8. — Toda persona tiene derecho a protección de ley contra ataques abusivos a su honra, a su reputación y a su vida privada o familiar.

Sección 9. — No se tomará o perjudicará la propiedad privada para uso público a no ser mediante el pago de una justa compensación y de acuerdo con la forma provista por ley. No se aprobará ley alguna autorizando a expropiar imprentas, maquinarias o material dedicados a publicaciones de cualquier índole. Los edificios donde se encuentren instaladas sólo podrán expropiarse previa declaración judicial de necesidad y utilidad pública mediante procedimientos que fijará la Ley, y sólo podrán tomarse antes de la declaración judicial, cuando se provea para la publicación un local adecuado en el cual pueda instalarse y continuar operando por un tiempo razonable.

Sección 10. — No se violará el derecho del pueblo a la protección de sus personas, casas, papeles y efectos contra registros, incautaciones y allanamientos irrazonables.

No se interceptará la comunicación telefónica.

Sólo se expedirán mandamientos autorizando registros, allanamientos o arrestos por autoridad judicial, y ello únicamente cuando exista causa probable apoyada en juramento o afirmación, describiendo particularmente el lugar o registrarse, y las personas a detenerse o las cosas a ocuparse.

Evidencia obtenida en violación de esta sección será inadmisible en los tribunales.

Sección 11. — En todos los procesos criminales, el acusado disfrutará del derecho a un juicio rápido y público, a ser notificado de la naturaleza y causa de la acusación recibiendo copia de la misma, a carearse con los testigos de cargo, a obtener la comparecencia compulsoria de testigos a su favor, a tener asistencia de abogado, y a gozar de la presunción de inocencia.

En los procesos por delito grave el acusado tendrá derecho a que su juicio se ventile ante un jurado imparcial compuesto por doce vecinos del distrito, quienes podrán rendir veredicto por mayoría de votos en el cual deberán concurrir no menos de nueve.

Nadie será obligado a incriminarse mediante su propio testimonio y el silencio del acusado no podrá tenerse en cuenta ni comentarse en su contra.

Nadie será puesto en riesgo de ser castigado dos veces por el mismo delito.

Todo acusado tendrá derecho a quedar en libertad bajo fianza antes de mediar un fallo condenatorio.

La detención preventiva antes del juicio no excederá de seis meses. Las fianzas y las multas no serán excesivas. Nadie será encarcelado por deuda.

Sección 12. — No existirá la esclavitud, ni forma alguna de servidumbre involuntaria salvo la que pueda imponerse por causa de delito, previa sentencia condenatoria. No se impondrán castigos crueles e inusitados. La suspensión de los derechos civiles incluyendo el derecho al sufragio cesará al cumplirse la pena impuesta.

No se aprobarán leyes *ex post facto* ni proyectos para condenar sin celebración de juicio.

Sección 13. — El auto de hábeas corpus será concedido con rapidez y libre de costas. No se suspenderá el privilegio del auto de hábeas corpus a no ser que, en casos de rebelión, insurrección o invasión, así lo requiera la seguridad pública. Sólo la Asamblea Legislativa tendrá el poder de suspender el privilegio del auto de hábeas corpus y las leyes que regulan su concesión.

La autoridad militar estará siempre subordinada a la autoridad civil.

Sección 14. — No se conferirán títulos de nobleza ni otras dignidades hereditarias. Ningún funcionario o empleado del Estado Libre Asociado aceptará regalos, donativos, condecoraciones o cargos de ningún país o funcionario extranjero sin previa autorización de la Asamblea Legislativa.

Sección 15. — No se permitirá el empleo de menores de catorce años en cualquier ocupación perjudicial a la salud o a la moral, o que de alguna manera amenace la vida o integridad física.

No se permitirá el ingreso de un menor de dieciséis años en una cárcel o presidio.

Sección 16. — Se reconoce el derecho de todo trabajador a escoger libremente su ocupación y a renunciar a ella, a recibir igual paga por igual trabajo, a un salario mínimo razonable, a protección contra riesgos para su salud o integridad personal en su trabajo o empleo, y a una jornada ordinaria que no exceda de ocho horas de trabajo. Sólo podrá trabajarse en exceso de este límite diario, mediante compensación extraordinaria que nunca será menor de una vez y media el tipo de salario ordinario según se disponga por ley.

Sección 17. — Los trabajadores de empresas, negocios y patronos privados y de agencias o instrumentalidades del gobierno que funcionen como empresa o negocios privados tendrán el derecho a organizarse y a negociar colectivamente con sus patronos por mediación de representantes de su propia y libre selección para promover su bienestar.

Sección 18. — A fin de asegurar el derecho a organizarse y a negociar colectivamente, los trabajadores de empresas, negocios y patronos privados y de agencias o instrumentalidades del gobierno que funcionen como empresas o negocios privados tendrán, en sus relaciones directas con sus propios patronos, el derecho a la huelga, a establecer piquetes y a llevar a cabo otras actividades concertadas legales.

Nada de lo contenido en esta sección menoscabará la facultad de la Asamblea Legislativa a aprobar leyes para casos de grave emergencia cuando estén claramente en peligro la salud o la seguridad pública, o los servicios públicos esenciales.

Sección 19. — La enumeración de derechos que antecede no se entenderá en forma restrictiva ni supone la exclusión de otros derechos pertenecientes al pueblo en una democracia, y no mencionados específicamente. Tampoco se entenderá como restrictiva de la facultad de la Asamblea Legislativa para aprobar leyes en protección de la vida, la salud y el bienestar del pueblo.

ARTICULO III

DEL PODER LEGISLATIVO

Sección 1. — El Poder Legislativo se ejercerá por una Asamblea Legislativa, que se compondrá de dos Cámaras — el Senado y la Cámara de Representante — cuyos miembros serán elegidos por votación directa en cada elección general.

Sección 2. — El Senado se compondrá de veintisiete Senadores y la Cámara de Representantes del cincuenta y un Representantes, excepto cuando dicha composición resultare aumentada a virtud de lo que se dispone en la Sección 7 de este Artículo.

Sección 3. — Para los fines de elección de los miembros a la Asamblea Legislativa, Puerto Rico estará dividido en ocho distritos senatoriales y en cuarenta distritos representativos. Cada distrito senatorial elegirá dos Senadores y cada distrito representativo un Representante.

Se elegirán además once Senadores y once Representantes por acumulación. Ningún elector podrá votar por más de un candidato a Senador por Acumulación ni por más de un candidato a Representante por Acumulación.

Sección 4. — En las primeras y siguientes elecciones bajo esta Constitución regirá la división en distritos senatoriales y representativos que aparece en el Artículo VIII. Dicha división será revisada después de cada censo decenal a partir del año 1960, por una Junta que estará compuesta del Juez Presidente del Tribunal Supremo como Presidente y de dos miembros adicionales nombrados por el Gobernador con el consejo y consentimiento del Senado. Los dos miembros adicionales no podrán pertenecer a un mismo partido político. Cualquier revisión mantendrá el número de distritos senatoriales y representativos aquí creados, los cuales estarán compuestos de territorios contiguos y compactos y se organizarán, hasta donde sea posible, sobre la base de población y medios de comunicación. Cada distrito senatorial incluirá siempre cinco distritos representativos.

La Junta adoptará sus acuerdos por mayoría y sus determinaciones regirán para las elecciones generales que se celebren después de cada revisión. La Junta quedará disuelta después de practicada cada revisión.

Sección 5. — Ninguna persona podrá ser miembro de la Asamblea Legislativa a menos que sepa leer y escribir cualquiera de los dos idiomas, español o inglés; sea ciudadano de los Estados Unidos y de Puerto Rico y haya residido en Puerto Rico por lo menos durante los dos años precedentes a la fecha de la elección o nombramiento. Tampoco podrán ser miembros del

Senado las personas que no hayan cumplido treinta años de edad, ni podrán ser miembros de la Cámara de Representantes las que no hayan cumplido veinticinco años de edad.

Sección 6. — Para ser electo o nombrado Senador o Representante por un distrito será requisito haber residido en el mismo durante no menos de un año con anterioridad a su elección o nombramiento. Cuando hubiere más de un distrito representativo en un municipio, se cumplirá este requisito con la residencia en el municipio.

Sección 7. — Cuando en una elección general resultaren electos más de dos terceras partes de los miembros de cualquiera de las cámaras por un solo partido o bajo una sola candidatura, según ambos términos se definan por ley, se aumentará el número de sus miembros en los siguientes casos:

(a) Si el partido o candidatura que eligió más de dos terceras partes de los miembros de cualquiera o ambas cámaras hubiese obtenido menos de dos terceras partes del total de los votos emitidos para el cargo de Gobernador, se aumentará el número de miembros del Senado o de la Cámara de Representantes o de ambos cuerpos, según fuere el caso, declarándose electos candidatos del partido o partidos de minoría en número suficiente hasta que la totalidad de los miembros del partido o partidos de minoría alcance el número de nueve en el Senado y de diecisiete en la Cámara de Representantes. Cuando hubiere más de un partido de minoría, la elección adicional de candidatos se hará en la proporción que guarde el número de votos emitidos para el cargo de Gobernador por cada uno de dichos partidos con el voto que para el cargo de Gobernador depositaron en total esos partidos de minoría.

Cuando uno o más partidos de minoría hubiese obtenido una representación en proporción igual o mayor a la proporción de votos alcanzada por su candidato a Gobernador, no participará en la elección adicional de candidatos hasta tanto se hubiese completado la representación que le correspondiese bajo estas disposiciones, a cada uno de los otros partidos de minoría.

(b) Si el partido o candidatura que eligió más de dos terceras partes de los miembros de cualquiera o ambas cámaras hubiese obtenido más de dos terceras partes del total de los votos emitidos para el cargo de Gobernador, y uno o más partidos de minoría no eligieron el número de miembros que les correspondía en el Senado o en la Cámara de Representantes o en ambos cuerpos, según fuere el caso, en proporción a los votos depositados por cada uno de ellos para el cargo de Gobernador, se declararán electos adicionalmente sus candidatos hasta completar dicha proporción en lo que fuere posible, pero los Senadores de todos los partidos de minoría no serán nunca, bajo esta disposición más de nueve ni los Representantes más de diecisiete.

Para seleccionar los candidatos adicionales de un partido de minoría, en cumplimiento de estas disposiciones, se considerarán, en primer término, sus candidatos por acumulación que no hubieren resultado electos, en el orden de los votos que hubieren obtenido y, en segundo término sus candidatos de distrito que, sin haber resultado electos, hubieren obtenido en sus distritos respectivos la más alta proporción en el número de votos depositados en relación con la proporción de los votos depositados a favor de otros candidatos no electos del mismo partido para un cargo igual en otros distritos.

Los Senadores y Representantes adicionales cuya elección se declare bajo esta sección serán considerados para todos los fines como Senadores o Representantes por Acumulación.

La Asamblea Legislativa adoptará las medidas necesarias para reglamentar estas garantías , y dispondrá la forma de adjudicar las fracciones que resultaren en la aplicación de las reglas contenidas en esta sección, así como el número mínimo de votos que deberá depositar un partido de minoría a favor de su candidato a Gobernador para tener derecho a la representación que en la presente se provee.

Sección 8. — El término del cargo de los Senadores y Representantes comenzará el día dos de enero inmediatamente siguiente a la fecha en que se celebre la elección general en la cual haya sido electos. Cuando surja una vacante en el cargo de Senador o Representante por un distrito, antes de los quince meses inmediatamente precedente a la fecha de la próxima elección general, el Gobernador convocará dentro de los treinta días siguientes a la fecha en que se produzca la vacante, a elección especial en dicho distrito, la cual habrá de celebrarse no más tarde de noventa días después de convocada, y la persona que resulte electa en dicha elección especial ocupará el cargo hasta la expiración del término de su antecesor. Cuando dicha vacante ocurriere en el transcurso de una sesión legislativa, o cuando la Asamblea Legislativa o el senado fueren convocados para una fecha anterior a la certificación del resultado de la elección especial, el presidente de la cámara correspondiente nombrará a la persona recomendada por el organismo directivo central del partido a que pertenecía el Senador o Representante cuyo cargo quedó vacante, para que ocupe el cargo hasta que se certifique la elección del candidato que resulte electo. Cuando la vacante ocurra dentro de los quince meses anteriores a una elección general, o cuando ocurra en el cargo de un Senador o un Representante por Acumulación, se cubrirá por el presidente de la cámara correspondiente, a propuesta del partido político a que pertenecía el Senador o Representante cuyo cargo estuviese vacante, con un candidato seleccionado en la misma forma en que lo fue su antecesor. La vacante de un cargo de Senador o Representante por Acumulación electo como candidato independiente, se cubrirá por elección en todos los distritos.

Sección 9. — Cada cámara será el único juez de la capacidad legal de sus miembros, de la validez de las actas y del escrutinio de su elección; elegirá sus funcionarios, adoptará las reglas propias de cuerpos legislativos para sus procedimientos y gobierno interno; y con la concurrencia de tres cuartas partes del número total de los miembros de que se compone, podrá decretar la expulsión de cualquiera de ellos por las mismas causas que se señalan para autorizar juicios de residencia en la sección 21 de este Artículo. Cada cámara elegirá un presidente de entre sus miembros respectivos.

Sección 10. — La Asamblea Legislativa será un cuerpo con carácter continuo durante el término de su mandato y se reunirá en sesión ordinaria cada año a partir del segundo lunes de enero. La duración de las sesiones ordinarias y los plazos para la radicación y la consideración de proyectos serán prescritos por ley. Cuando el Gobernador convoque a la Asamblea Legislativa a sesión extraordinaria sólo podrá considerarse en ella los asuntos especificados en la convocatoria o en mensaje especial que el Gobernador le envíe en el curso de la sesión, la cual no podrá extenderse por más de veinte días naturales.

Sección 11. — Las sesiones de las cámaras serán públicas.

Sección 12. — Una mayoría del número total de los miembros que componen cada cámara constituirá quórum, pero un número menor podrá recesar de día en día y tendrá autoridad para compeler la asistencia de los miembros ausentes.

Sección 13. — Las cámaras legislativas se reunirán en el Capitolio de Puerto Rico y ninguna de ellas podrá suspender sus sesiones por más de tres días consecutivos sin el consentimiento de la otra.

Sección 14. — Ningún miembro de la Asamblea Legislativa será arrestado mientras esté en sesión la cámara de la cual forma parte, ni durante los quince días anteriores o siguientes a cualquier sesión, excepto por traición, delito grave, o alteración de la paz; y todo miembro de la Asamblea Legislativa gozará de inmunidad parlamentaria por sus votos y expresiones en una u otra cámara o en cualquiera de sus comisiones.

Sección 15. — Ningún Senador o Representante podrá ser nombrado, durante el término por el cual fue electo o designado, para ocupar en el Gobierno de Puerto Rico, sus municipios o instrumentalidades, cargo civil alguno creado, o mejorado en su sueldo, durante dicho término. Ninguna persona podrá ocupar un cargo en el Gobierno de Puerto Rico, sus municipios o instrumentalidades y ser al mismo tiempo Senador o Representante. Estas disposiciones no impedirán que un legislador sea designado para desempeñar funciones ad honorem.

Sección 16. — La Asamblea Legislativa tendrá facultad para crear, consolidar o reorganizar departamentos ejecutivos y definir sus funciones.

Sección 17. — Ningún proyecto de ley se convertirá en ley a menos que se imprima, se lea, se remita a comisión y ésta lo devuelva con un informe escrito; pero la cámara correspondiente podrá descargar a la comisión del estudio e informe de cualquier proyecto y proceder a la consideración del mismo. Las cámaras llevarán libros de actas donde harán constar lo relativo al trámite de los proyectos y las votaciones emitidas a favor y en contra de los mismos. Se dará publicidad a los procedimientos legislativos en un diario de sesiones, en la forma que se determine por ley. No se aprobará ningún proyecto de ley, con excepción de los de presupuesto general, que contenga más de un asunto, el cual deberá ser claramente expresado en su título, y toda aquella parte de una ley cuyo asunto no haya sido expresado en el título será nula. La ley de presupuesto general sólo podrá contener asignaciones y reglas para el desembolso de las mismas. Ningún proyecto de ley será enmendado de manera que cambie su propósito original o incorpore materias extrañas al mismo. Al enmendar cualquier artículo o sección de una ley, dicho artículo o sección será promulgado en su totalidad tal como haya quedado enmendado. Todo proyecto de ley para obtener rentas se originará en la Cámara de Representantes, pero el Senado podrá proponer enmiendas o convenir en ellas como si se tratare de cualquier otro proyecto de ley.

Sección 18. — Se determinará por ley los asuntos que puedan ser objeto de consideración mediante resolución conjunta, pero toda resolución conjunta seguirá el mismo trámite de un proyecto de ley.

Sección 19. — Cualquier proyecto de ley que sea aprobado por una mayoría del número total de los miembros que componen cada cámara se someterá al Gobernador y se convertirá en ley si éste lo firma o si no lo devuelve con sus objeciones a la cámara de origen dentro de diez días (exceptuando los domingos) contados a partir de la fecha en que lo hubiese recibido.

Cuando el Gobernador devuelva un proyecto, la cámara que lo reciba consignará las objeciones del Gobernador en el libro de actas y ambas cámaras podrán reconsiderar el proyecto, que de ser aprobado por dos terceras partes del número total de los miembros que componen cada una de ellas, se convertirá en ley.

Si la Asamblea Legislativa levanta sus sesiones antes de expirar el plazo de diez días de haberse sometido un proyecto al Gobernador, éste quedará relevado de la obligación de devolverlo con sus objeciones, y el proyecto solo se convertirá en ley de firmarlo el Gobernador dentro de los treinta días de haberlo recibido.

Toda aprobación final o reconsideración de un proyecto será en votación por lista.

Sección 20. — Al aprobar cualquier proyecto de ley que asigne fondos en más de una partida, el Gobernador podrá eliminar una o más partidas o disminuir las mismas, reduciendo al mismo tiempo los totales correspondientes.

Sección 21. — La Cámara de Representantes tendrá el poder exclusivo de iniciar procesos de residencia y con la concurrencia de dos terceras partes del número total de sus miembros formular acusación. El Senado tendrá el poder exclusivo de juzgar y dictar sentencia en todo proceso de residencia; y al reunirse para tal fin los Senadores actuarán a nombre del pueblo y lo harán bajo juramento o afirmación. No se pronunciará fallo condenatorio en un juicio de residencia sin la concurrencia de tres cuartas partes del número total de los miembros que componen el Senado y la sentencia se limitará a la separación del cargo. La persona residenciada quedará expuesta y sujeta a acusación, juicio, sentencia y castigo conforme a la Ley. Serán causas de residencia la traición, el soborno, otros delitos graves, y aquellos delitos menos grave que impliquen depravación. El Juez Presidente del Tribunal Supremo presidirá todo juicio de residencia del Gobernador.

Las cámaras legislativas podrán ventilar procesos de residencia en sus sesiones ordinarias o extraordinarias. Los presidentes de las cámaras a solicitud por escrito de dos terceras partes del número total de los miembros que componen la Cámara de Representantes, deberán convocarlas para entender en tales procesos.

Sección 22. — Habrá un Contralor que será nombrado por el Gobernador con el consejo y consentimiento de la mayoría del número total de los miembros que componen cada Cámara. El Contralor reunirá los requisitos que se prescriban por ley; desempeñará su cargo por un término de diez años y hasta que su sucesor sea nombrado y tome posesión. El Contralor fiscalizará todos los ingresos, cuentas y desembolsos del Estado, de sus agencias e instrumentalidades y de los municipios, para determinar si se han hecho de acuerdo con la ley. Rendirá informes anuales y todos aquellos informes especiales que le sean requeridos por la Asamblea Legislativa o el Gobernador.

En el desempeño de sus deberes el Contralor estará autorizado para tomar juramentos y declaraciones y para obligar, bajo apercibimiento de desacato, a la comparecencia de testigos y a la producción de libros, cartas, documentos, papeles, expedientes, y todos los demás objetos que sean necesarios para un completo conocimiento del asunto bajo investigación.

El Contralor podrá ser separado de su cargo por las causas y mediante el procedimiento establecido en la sección precedente.

ARTICULO IV

DEL PODER EJECUTIVO

Sección 1. — El poder Ejecutivo se ejercerá por un Gobernador, quien será elegido por voto directo en cada elección general.

Sección 2. — El Gobernador ejercerá su cargo por el término de cuatro años a partir del día dos de enero del año siguiente al de su elección y hasta que su sucesor sea electo y tome posesión. Residirá en Puerto Rico, cuya ciudad tendrá su despacho.

Sección 3. — Nadie podrá ser Gobernador a menos que, a la fecha de la elección, haya cumplido treinta y cinco años de edad, y sea, y haya sido durante los cinco años precedentes, ciudadano de los Estados Unidos de América y ciudadano y residente bona fide de Puerto Rico.

Sección 4. — Los deberes, funciones y atribuciones del Gobernador serán:

Cumplir y hacer cumplir las leyes.

Convocar a la Asamblea Legislativa o el Senado a sesión extraordinaria cuando a su juicio los intereses públicos así lo requieran.

Nombrar, en la forma que se disponga por esta Constitución o por ley, a todos los funcionarios para cuyo nombramiento esté facultado. El Gobernador podrá hacer nombramientos cuando la Asamblea Legislativa no esté en sesión. Todo nombramiento que requiera el consejo y consentimiento del Senado o de ambas cámaras quedará sin efecto al levantarse la siguiente sesión ordinaria.

Ser comandante en jefe de la milicia.

Llamar la milicia y convocar el *posse comitatus* a fin de impedir o suprimir cualquier grave perturbación del orden público, rebelión o invasión.

Proclamar la ley marcial cuando la seguridad pública lo requiera en casos de rebelión o invasión o inminente peligro de ellas. La Asamblea Legislativa deberá inmediatamente reunirse por iniciativa propia para ratificar o revocar la proclama.

Suspender la ejecución de sentencia en casos criminales, conceder indultos, conmutar penas y condonar total o parcialmente multas y confiscaciones por delitos cometidos en violación de las leyes de Puerto Rico. Esta facultad no se extiende a procesos de residencia.

Sancionar o desaprobar con arreglo a esta Constitución, las resoluciones conjuntas y los proyectos de ley aprobados por la Asamblea Legislativa.

Presentar a la Asamblea Legislativa, al comienzo de cada sesión ordinaria, un mensaje sobre la situación del Estado y someterle además un informe sobre las condiciones del Tesoro de Puerto Rico y los desembolsos propuestos para el año económico siguiente. Dicho informe contendrá los datos necesarios para la formulación de un programa de legislación.

Ejercer las otras facultades y atribuciones y cumplir los demás deberes que se le señalen por esta Constitución o por ley.

Sección 5. — Para el ejercicio del Poder Ejecutivo el Gobernador estará asistido de Secretarios de Gobierno que nombrará con el consejo y consentimiento del Senado. El nombramiento del Secretario de Estado requerirá, además, el consejo y consentimiento de la Cámara de Representantes, y la persona nombrada deberá reunir los requisitos establecidos en la sección 3 de este Artículo. Los Secretarios de Gobierno constituirán colectivamente un consejo consultivo del Gobernador que se denominará Consejo de Secretarios.

Sección 6. — Sin perjuicio de la facultad de la Asamblea Legislativa para crear, reorganizar y consolidar departamentos ejecutivos de gobierno, y para definir sus funciones, se establecen los siguientes: de Estado, de Justicia, de Instrucción Pública, de Salud, de Hacienda, de Trabajo, de Agricultura y Comercio y de Obras Públicas. Cada departamento ejecutivo estará a cargo de un Secretario de Gobierno.

Sección 7. — Cuando ocurra una vacante en el cargo de Gobernador producida por muerte, renuncia, destitución, incapacidad total y permanente, o por cualquier otra falta absoluta, dicho cargo pasará al Secretario de Estado, quien lo desempeñará por el resto del término y hasta que un nuevo Gobernador sea electo y tome posesión. La ley dispondrá cuál de los Secretarios de Gobierno ocupará el cargo de Gobernador en caso de que simultáneamente quedaren vacantes los cargos de Gobernador y de Secretario de Estado.

Sección 8. — Cuando por cualquier causa que produzca ausencia de carácter transitorio el Gobernador esté temporalmente impedido de ejercer sus funciones, lo sustituirá, mientras dure el impedimento, el Secretario de Estado. Si por cualquier razón el Secretario de Estado no pudiere ocupar el cargo, lo ocupará el Secretario de Gobierno que se determine por ley.

Sección 9. — Cuando el Gobernador electo no tomase posesión de su cargo, o habiéndolo hecho ocurra una vacante absoluta en el mismo sin que dicho Gobernador haya nombrado un Secretario de Estado o cuando habiéndolo nombrado éste no haya tomado posesión, la Asamblea Legislativa electa, al reunirse en su primera sesión ordinaria, elegirá por mayoría del número total de los miembros que componen cada cámara, un Gobernador y éste desempeñará el cargo hasta que su sucesor sea electo en la siguiente elección general y tome posesión.

Sección 10. — El Gobernador podrá ser destituido por las causas y mediante el procedimiento que esta Constitución establece en la sección 21 del Artículo III.

ARTICULO V

DEL PODER JUDICIAL

Sección 1. — El poder Judicial de Puerto Rico se ejercerá por un Tribunal Supremo, y por aquellos otros tribunales que se establezcan por ley.

Sección 2. — Los tribunales de Puerto Rico constituirán un sistema judicial unificado en lo concerniente a jurisdicción , funcionamiento y administración. La Asamblea Legislativa, en cuanto no resulte incompatible con esta Constitución, podrá crear y suprimir tribunales, con excepción del Tribunal Supremo, y determinará su competencia y organización.

Sección 3. — El Tribunal Supremo será el tribunal de última instancia en Puerto Rico y se compondrá de un juez presidente y cuatro jueces asociados. El número de sus jueces sólo podrá ser variado por ley, a solicitud del propio Tribunal Supremo.

Sección 4. — El Tribunal Supremo funcionará, bajo reglas de su propia adopción, en pleno o dividido en salas compuestas de no menos de tres jueces. Ninguna ley se declarará inconstitucional a no ser por una mayoría del número total de los jueces de que esté compuesto el tribunal de acuerdo con esta Constitución o con la ley.

Sección 5. — El Tribunal Supremo, cada una de sus salas, así como cualquiera de sus jueces, podrán conocer en primera instancia de recursos de hábeas corpus y de aquellos otros recursos y causas que se determinen por ley.

Sección 6. — El Tribunal Supremo adoptará, para los tribunales, reglas de evidencia y de procedimiento civil y criminal que no menoscaben, amplíen o modifiquen derechos sustantivos de las partes. Las reglas así adoptadas se remitirán a la Asamblea Legislativa al comienzo de su próxima sesión ordinaria y regirán sesenta días después de la terminación de dicha sesión, salvo desaprobación por la Asamblea Legislativa, la cual tendrá facultad, tanto en dicha sesión como posteriormente, para enmendar, derogar o complementar cualquiera de dichas reglas, mediante ley específica a tal efecto.

Sección 7. — El Tribunal Supremo adoptará reglas para la administración de los tribunales las que estarán sujetas a las leyes relativas a suministros, personal, asignación y fiscalización de fondos, y a otras leyes aplicables en general al gobierno. El Juez Presidente dirigirá la administración de los tribunales y nombrará un director administrativo, quien desempeñará su cargo a discreción de dicho magistrado.

Sección 8. — Los jueces serán nombrados por el Gobernador con el consejo y consentimiento del Senado. Los jueces del Tribunal Supremo no tomarán posesión de sus cargos hasta que sus nombramientos sean confirmados por el Senado y los desempeñarán mientras observen buena conducta. Los términos de los cargos de los demás jueces se fijarán por ley y no podrán ser de menor duración que la prescrita para los cargos de jueces de igual o equivalente categoría existentes en la fecha que comience a regir esta Constitución. Todo lo relativo al nombramiento de los demás funcionarios y de los empleados de los tribunales, se determinará por ley.

Sección 9. — Nadie será nombrado juez del Tribunal Supremo a menos que sea ciudadano de los Estado Unidos y de Puerto Rico, haya sido admitido al ejercicio de la profesión de abogado en Puerto Rico por lo menos diez años antes del nombramiento y haya residido en Puerto Rico durante los cinco años inmediatamente anteriores al mismo.

Sección 10. — La Asamblea Legislativa establecerá un sistema de retiro para los jueces, retiro que será obligatorio cuando hubieren cumplido setenta años de edad.

Sección 11. — Los jueces del Tribunal Supremo podrán ser destituidos por las causas y mediante el procedimiento que esta Constitución establece en la sección 21 del Artículo III. Los jueces de los demás tribunales podrán ser destituidos por el Tribunal Supremo por las causas y mediante el procedimiento que se disponga por ley.

Sección 12. — Ningún juez aportará dinero, en forma directa o indirecta, a organizaciones o partidos políticos, ni desempeñará cargos en la dirección de los mismos o participará en campañas políticas de clase alguna, ni podrá postularse para un cargo público electivo a menos que haya renunciado al de juez por lo menos seis meses antes de su nominación.

Sección 13. — De modificarse o eliminarse por ley un tribunal o una sala o sección del mismo, la persona que en él ocupare un cargo de juez continuará desempeñándolo durante el resto del término por el cual fue nombrado, y ejercerá aquellas funciones judiciales que le asigne el Juez Presidente del Tribunal Supremo.

ARTICULO VI

DISPOSICIONES GENERALES

Sección 1. — La Asamblea Legislativa tendrá facultad para crear, suprimir, consolidar y reorganizar municipios, modificar sus límites territoriales y determinar lo relativo a su régimen y función; y podrá autorizarlos, además, a desarrollar programas de bienestar general y a crear aquellos organismos que fueren necesarios a tal fin.

Ninguna ley para suprimir o consolidar municipios tendrá efectividad hasta que sea ratificada, en referéndum, por la mayoría de los electores capacitados que participen en el mismo en cada uno de los municipios a suprimirse o consolidarse. La forma del referéndum se determinará por ley que deberá incluir aquellos procedimientos aplicables de la legislación electoral vigente a la fecha de la aprobación de la ley.

Sección 2. — El poder del Estado Libre Asociado para imponer y cobrar contribuciones y autorizar su imposición y cobro por los municipios se ejercerá según se disponga por la Asamblea Legislativa, y nunca será rendido o suspendido. El poder del Estado Libre Asociado de Puerto Rico para contraer y autorizar deudas se ejercerá según se disponga por la Asamblea Legislativa, pero ninguna obligación directa del Estado Libre Asociado de Puerto Rico por dinero tomado a préstamo directamente por el Estado Libre Asociado de Puerto Rico evidenciada mediante bonos o pagarés para el pago de la cual la buena fe, el crédito y el poder de imponer contribuciones del Estado Libre Asociado de Puerto Rico fueren empeñados será emitida por el Estado Libre Asociado de Puerto Rico si el total de (i) el monto del principal de e intereses sobre dichos bonos y pagarés, junto con el monto del principal de e intereses sobre la totalidad de tales bonos y pagarés hasta entonces emitidos por el Estado Libre Asociado y en circulación, pagaderos en cualquier año económico y (ii) cualesquiera cantidades pagadas por el Estado Libre Asociado en el año económico inmediatamente anterior al año económico corriente en concepto de principal e intereses correspondientes a cualesquiera obligaciones evidenciadas mediante bonos o pagarés garantizadas por el Estado Libre Asociado, excediere el 15% del promedio del monto total de las rentas anuales obtenidas de acuerdo con las disposiciones de las leyes del Estado Libre Asociado e ingresadas en el Tesoro de Puerto Rico en los dos años económicos inmediatamente anteriores al año económico corriente; y ninguno de dichos bonos o pagarés emitidos por el Estado Libre Asociado para cualquier fin que no fuere facilidades de vivienda vencerá con posterioridad a un término de 30 años desde la fecha de su emisión y ningún bono o pagaré emitido para fines de vivienda vencerá con posterioridad a un término de 30 años desde la fecha de su emisión; y el Estado Libre Asociado no garantizará obligación alguna evidenciada mediante bonos o pagarés si el total de la cantidad pagadera en cualquier año económico en concepto de principal e intereses sobre la totalidad de las antes referidas obligaciones directas hasta entonces emitidas por el Estado Libre Asociado y en circulación y las cantidades a que se hace referencia en la cláusula (ii) excediere el 15 por ciento del promedio del monto total de dichas rentas anuales.

La Asamblea Legislativa fijará límites para la emisión de obligaciones directas por cualquier municipio de Puerto Rico por dinero tomado a préstamo directamente por dicho municipio evidenciadas mediante bonos o pagarés para el pago de las cuales la buena fe, el crédito y el poder para imponer contribuciones de dicho municipio fueren empeñados; disponiéndose, sin embargo, que ninguno de dichos bonos o pagarés será emitido por municipio alguno en una cantidad que, junto con el monto de la totalidad de tales bonos y pagarés hasta entonces emitidos por dicho municipio y en circulación, exceda el por ciento determinado por la Asamblea Legislativa, el cual no será menor del cinco por ciento (5%) ni mayor del diez por ciento (10%) del valor total de la tasación de la propiedad situada en dicho municipio.

El Secretario de Hacienda podrá ser requerido para que destine los recursos disponibles incluyendo sobrantes al pago de los intereses sobre la deuda pública y la amortización de la misma en cualquier caso al cual fuere aplicable la Sección 8 de este Artículo VI mediante demanda incoada por cualquier tenedor de bonos o pagarés emitidos en evidencia de la misma.

Sección 3. — Las reglas para imponer contribuciones serán uniformes en Puerto Rico.

Sección 4. — Las elecciones generales se celebrarán cada cuatro años en el día del mes de noviembre que determine la Asamblea Legislativa. En dichas elecciones serán elegidos el Gobernador, los miembros de la Asamblea Legislativa y los demás funcionarios cuya elección en esa fecha disponga por ley.

Será elector toda persona que haya cumplido 18 años de edad, y reúna los demás requisitos que se determine por ley. Nadie será privado del derecho al voto por no saber leer o escribir o por no poseer propiedad.

Se dispondrá por ley todo lo concerniente al proceso electoral y de inscripción de electores, así como lo relativo a los partidos políticos y candidaturas.

Todo funcionario de elección popular será elegido por voto directo y se declarará electo aquel candidato para un cargo que obtenga un número mayor de votos que el obtenido por cualquiera de los demás candidatos para el mismo cargo.

Sección 5. — Las leyes deberán ser promulgadas conforme al procedimiento que se prescriba por ley y contendrán sus propios términos de vigencia.

Sección 6. — Cuando a la terminación de un año económico no se hubiesen aprobado las asignaciones necesarias para los gastos ordinarios de funcionamiento del gobierno y para el pago de intereses y amortización de la deuda pública durante el siguiente año económico, continuarán rigiendo las partidas consignadas en la últimas leyes aprobadas para los mismos fines y propósitos, en todo lo que fueren aplicables, y el Gobernador autorizará los desembolsos necesarios a tales fines hasta que se aprueben las asignaciones correspondientes.

Sección 7. — Las asignaciones hechas para un año económico no podrán exceder de los recursos totales calculados para dicho año económico, a menos que se provea por ley para la imposición de contribuciones suficientes para cubrir dichas asignaciones.

Sección 8. — Cuando los recursos disponibles para un año económico no basten para cubrir las asignaciones aprobadas para ese año, se procederá en primer término, al pago de intereses y amortización de la deuda pública, y luego se harán los demás desembolsos de acuerdo con la norma de prioridades que se establezca por ley.

Sección 9. — Sólo se dispondrá de las propiedades y fondos públicos para fines públicos y para sostenimiento y funcionamiento de las instituciones del estado, y en todo caso por autoridad de ley.

Sección 10. — Ninguna ley concederá compensación adicional a un funcionario, empleado, agente o contratista por servicios al gobierno, después que los servicios hayan sido prestados o después que se haya formalizado el contrato. Ninguna ley prorrogará el término de un funcionario público ni disminuirá su sueldo a emolumentos después de su elección o nombramiento. Ninguna persona podrá recibir sueldo por más de un cargo o empleo en el gobierno de Puerto Rico.

Sección 11. — Los sueldos del Gobernador, de los Secretarios de Gobierno, de los miembros de la Asamblea Legislativa, del Contralor y de los jueces se fijarán por ley especial y, con excepción del sueldo de los miembros de la Asamblea Legislativa, no podrán ser disminuidos durante el término para el cual fueron electos o nombrados. Los del Gobernador y el Contralor no podrán ser aumentados durante dicho término. Ningún aumento en los sueldos de los miembros de la Asamblea Legislativa tendrá efectividad hasta vencido el término de la Asamblea Legislativa que lo apruebe. Cualquier reducción de los sueldos de los miembros de la Asamblea Legislativa sólo tendrá efectividad durante el término de la Asamblea Legislativa que la apruebe.

Sección 12. — Los edificios y propiedades pertenecientes al Estado Libre Asociado que hasta ahora han sido usados y ocupados por el Gobernador como Jefe Ejecutivo, y aquellos que usare y ocupare en la misma capacidad, no devengarán rentas.

Sección 13. — El procedimiento para otorgar franquicias, derechos, privilegios y concesiones de carácter público o cuasi público será determinado por ley, pero toda concesión de esta índole a una persona o entidad privada deberá ser aprobada por el Gobernador o por el funcionario ejecutivo en quien él delegue. Toda franquicia, derecho, privilegio o concesión de carácter público o cuasi público estará sujeta o enmienda, alteración o revocación según se determine por ley.

Sección 14. — Ninguna corporación estará autorizada para efectuar negocios de compra y venta de bienes raíces; ni se le permitirá poseer o tener dicha clase de bienes a excepción de aquéllos que fuesen racionalmente necesarios para poder llevar adelante los propósitos a que obedeció su creación; y el dominio y manejo de terrenos de toda corporación autorizada para dedicarse a la agricultura estarán limitados, por su carta constitutiva, a una entidad que no exceda de quinientos acres; y esta disposición se entenderá en el sentido de impedir a cualquier miembro de una corporación agrícola que tenga interés de ningún género en otra corporación de igual índole.

Podrán, sin embargo, las corporaciones efectuar préstamos, con garantías sobre bienes raíces y adquirir éstos cuando sera necesario para el cobro de los préstamos; pero deberán disponer de dichos bienes raíces así obtenidos dentro de los cinco años de haber recibido el título de propiedad de los mismos.

Las corporaciones que no se hayan organizado en Puerto Rico, pero que hagan negocios en Puerto Rico, estarán obligadas a cumplir lo dispuesto en esta sección, hasta donde sea aplicable.

Estas disposiciones no impedirán el dominio, la posesión o el manejo de terrenos en exceso de quinientos acres por el Estado Libre Asociado y sus agencias o instrumentalidades.

Sección 15. — La Asamblea Legislativa determinará todo lo concerniente a la Bandera, el Escudo y el Himno del Estado Libre Asociado. Una vez así establecidos, cualquier ley que los cambie no comenzará a regir hasta un año después de celebradas las elecciones generales siguientes a la fecha de la aprobación de dicha ley.

Sección 16. — Todos los funcionarios y empleados del Estado Libre Asociado, sus agencias, instrumentalidades y subdivisiones políticas prestarán antes de asumir las funciones de sus cargos, juramento de fidelidad a la Constitución de los Estados Unidos de América y a la Constitución y a las leyes del Estado Libre Asociado de Puerto Rico.

Sección 17. — En casos de invasión, rebelión, epidemia o cualesquiera otros que provoquen un estado de emergencia, el Gobernador podrá convocar a la Asamblea Legislativa para reunirse fuera del sitio en que tengan su asiento las cámaras, siempre con sujeción a la aprobación o desaprobación de la Asamblea Legislativa. Así mismo podrá ordenar el traslado e instalación provisional del Gobierno, con sus agencias, instrumentalidades y organismos fuera de la sede del gobierno, por el tiempo que dure la emergencia.

Sección 18. — Toda acción criminal en los tribunales del Estado Libre Asociado se instruirá a nombre y por autoridad de "El Pueblo de Puerto Rico" mientras otra cosa no se dispusiere por ley.

Sección 19. — Será política pública del Estado Libre Asociado la más eficaz conservación de sus recursos naturales, así como el mayor desarrollo y aprovechamiento de los mismos para el beneficio general de la comunidad; la conservación y mantenimiento de los edificios y lugares que sean declarados de valor histórico o artístico por la Asamblea Legislativa; reglamentar las instituciones penales para que sirvan a sus propósitos en forma efectiva y propender, dentro de los recursos disponibles, al tratamiento adecuado de los delincuentes para hacer posible su rehabilitación moral y social.

ARTICULO VII

DE LAS ENMIENDAS A LA CONSTITUCION

Sección 1. — La Asamblea Legislativa podrá proponer enmiendas a la Constitución mediante resolución concurrente que se apruebe por no menos de dos terceras partes del número total de los miembros de que se compone cada cámara. Toda proposición de enmienda se someterá a los electores capacitado en referéndum especial, pero la Asamblea Legislativa podrá, siempre que la resolución concurrente se apruebe por no menos de tres cuartas partes del número total de los miembros de que se compone cada cámara, disponer que el referéndum se celebre al mismo tiempo que la elección general siguiente. Cada proposición de enmienda deberá votarse separadamente y en ningún caso se podrá someter más de tres proposiciones de enmienda en un mismo referéndum. Toda enmienda contendrá sus propios términos de vigencia y formará parte

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de esta Constitución si es ratificada por el voto de la mayoría de los electores que voten sobre el particular. Aprobada una proposición de enmienda, deberá publicarse con tres meses de antelación, por lo menos, a la fecha del referéndum.

Sección 2. — La Asamblea Legislativa podrá, mediante resolución concurrente aprobada por dos terceras partes del número total de los miembros de que se compone cada cámara, consultar a los electores capacitados si desean que se convoque a una convención constituyente para hacer una revisión de esta Constitución. La consulta se hará mediante referéndum que se celebrará al mismo tiempo que la elección general; y si se deposita a favor de la revisión una mayoría de los votos emitidos sobre el particular, se procederá a la revisión en Convención Constituyente elegida en la forma que se disponga por ley. Toda revisión de esta Constitución deberá someterse a los electores capacitados en referéndum especial para su aprobación o rechazo por mayoría de los votos que se emitan.

Sección 3. — Ninguna enmienda a esta Constitución podrá alterar la forma republicana de gobierno que por ella se establece o abolir su Carta de Derechos. Cualquier enmienda o revisión de esta constitución deberá ser compatible con la resolución decretada por el Congreso de los Estados Unidos aprobando esta constitución, con las disposiciones aplicables de la Constitución de los Estados Unidos, con la ley de Relaciones Federales con Puerto Rico y con la Ley Pública 600 del Congreso Octogésimoprimero, adoptada con el carácter de un convenio.

ARTICULO VIII

DE LOS DISTRITOS SENATORIALES Y DE LOS REPRESENTATIVOS

Sección 1. — Los distritos senatoriales y representativos serán los siguientes:

I. — DISTRITO SENATORIAL DE SAN JUAN, que se compondrá de los siguientes Distritos Representativos: 1. — La Capital de Puerto Rico excluyendo los actuales precintos electorales de Santurce y Río Piedras; 2. — Las zonas electorales números 1 y 2 del actual precinto de Santurce; 3. — La zona electoral número 3 del actual precinto de Santurce; 4. — La zona electoral número 4 del actual precinto de Santurce y 5. — Los barrios Hato Rey, Puerto Nuevo y Caparra Heights, de la Capital de Puerto Rico.

II. — DISTRITO SENATORIAL DE BAYAMÓN, que se compondrá de los siguientes Distritos Representativos: 6. — El municipio de Bayamón; 7. — Los municipios de Carolina y Trujillo Alto; 8. — El actual precinto electoral de Río Piedras excluyendo los barrios Hato Rey, Puerto Nuevo y Caparra Heights de la Capital de Puerto Rico; 9. — Los municipios de Cataño, Guaynabo y Toa Baja y 10. — Los municipios de Toa Alta, Corozal y Naranjito.

III. — DISTRITO SENATORIAL DE ARECIBO, que se compondrá de los siguientes Distritos Representativos: 11. — Los municipios de Vega Baja, Vega Alta y Dorado; 12. — Los municipios de Manatí y Barceloneta; 13. — Los municipios de Ciales y Morovis; 14. — El municipio de Arecibo y 13. — El Municipio de Utuado.

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IV. — DISTRITO SENATORIAL DE AGUADILLA, que se compondrá de los siguientes Distritos Representativos: 16. — Los municipios de Camuy, Hatillo y Quebradillas; 17. — Los municipios de Aguadilla e Isabela; 18. — Los municipios de San Sebastián y Moca; 19. — Los municipios de Lares, Las Marías y Maricao y 20. — Los municipios de Añasco, Aguada y Rincón.

V. — DISTRITO SENATORIAL DE MAYAGÜEZ, que se compondrá de los siguientes Distritos Representativos: 21. — El municipio de Mayagüez; 22. — Los municipios de Cabo Rojo, Hormigueros y Lajas; 23. — Los municipios de San Germán y Sabana Grande; 24. — Los municipios de Yauco y Guánica y 25. — Los municipios de Guayanilla y Peñuelas.

VI. — DISTRITO SENATORIAL DE PONCE, que se compondrá de los siguientes Distritos Representativos; 26. — Los barrios primero, segundo, tercero, cuarto, quinto, sexto y la Playa de la ciudad de Ponce, del municipio de Ponce; 27. — Todo el municipio de Ponce, exceptuando los barrios primero, segundo, tercero, cuarto, quinto y sexto y la Playa de la ciudad de Ponce; 28. — Los municipios de Adjuntas y Jayuya; 29. — Los muncipios de Juana Díaz, Santa Isabel y Villalba y 30. — Los municipios de Coamo y Orocovis.

VII. — DISTRITO SENATORIAL DE GUAYAMA, que se compondrá de los siguientes Distritos Representativos: 31. — Los municipios de Aibonito, Barranquitas y Comerío; 32. — Los municipios de Cayey y Cidra; 33. — Los municipios de Caguas y Aguas Buenas; 34. — Los municipios de Guayama y Salinas y 35. — Los municipios de Patillas, Maunabo y Arroyo.

VIII. — DISTRITO SENATORIAL DE HUMACAO, que se compondrá de los siguientes Distritos Representativos: 36. — Los municipios de Humacao y Yabucoa; 37. — Los muncipios de Juncos, Gurabo y San Lorenzo; 38. — Los municipios de Naguabo, Ceiba y Las Piedras; 39. — Los muncipios de Fajardo, Vieques y la Isla de Culebra y 40. — Los muncipios de Río Grande, Loíza y Luquillo.

Sección 2. — Las zonas electorales números 1, 2, 3, y 4 incluídas en tres distritos representativos comprendidos en el distrito senatorial de San Juan, son las mismas actualmente existentes para fines de organización electoral, en el segundo precinto de San Juan.

ARTICULO IX

DISPOSICIONES TRANSITORIAS

Sección 1. — Al comenzar a regir esta Constitución todas las leyes que no estén en conflicto con la misma continuarán en vigor íntegramente hasta que sean enmendadas o derogadas o hasta que cese su vigencia de acuerdo con sus propias disposiciones.

Salvo que otra cosa disponga esta Constitución, la responsabilidad civil y criminal, los derechos, franquicias, concesiones, privilegios, reclamaciones, acciones, causas de acción, contratos y los procesos civiles, criminales y administrativos subsistirán no obstante la vigencia de esta Constitución.

Sección 2. — Todos los funcionarios que ocupen cargos por elección o nombramiento a la fecha en que comience a regir esta Constitución, continuarán en el desempeño de los mismos y continuarán ejerciendo las funciones de sus cargos que no sean incompatibles con esta Constitución, a menos que las funciones de los mismos sean abolidas o hasta tanto sus sucesores sean seleccionados y tomen posesión de acuerdo con esta Constitución y con las leyes aprobadas bajo la autoridad de la misma.

Sección 3. — Independientemente del límite de edad fijado por esta Constitución para el retiro obligatorio, todos los jueces de los tribunales de Puerto Rico que estén desempeñando sus cargos a la fecha en que comience a regir esta Constitución continuarán como jueces hasta la expiración del término por el cual fueron nombrados y los del Tribunal Supremo continuarán en sus cargos mientras observen buena conducta.

Sección 4. — El Estado Libre Asociado de Puerto Rico será sucesor de El Pueblo de Puerto Rico a todos los efectos, incluyendo, pero sin que se entienda como una limitación, el cobro y pago de deudas y obligaciones de acuerdo con los términos de las mismas.

Sección 5. — En lo sucesivo la expresión "ciudadano del Estado Libre Asociado de Puerto Rico" sustituirá a la expresión "ciudadano de Puerto Rico"según ésta ha sido usada antes de la vigencia de esta Constitución.

Sección 6. — Los partidos políticos continuarán disfrutando de todos los derechos que les reconozca la ley electoral, siempre que reúnan los requisitos mínimos exigidos para la inscripción de nuevos partidos por la ley vigente al comenzar a regir esta Constitución. La Asamblea Legislativa, cinco años después de estar en vigor la Constitución, podrá cambiar estos requisitos, pero cualquier ley que aumente los mismos, no será efectiva hasta después de celebrada la elección general siguiente a la aprobación de la misma.

Sección 7. — La Asamblea Legislativa podrá aprobar las leyes que fueren necesarias para complementar y hacer efectivas estas disposiciones transitorias a fin de asegurar el funcionamiento del Gobierno, hasta que los funcionarios que en esta Constitución se proveen sean electos o nombrados y tomen posesión de sus cargos, y hasta que esta Constitución adquiera vigencia en todos sus aspectos.

Sección 8. — De crearse un Departamento de Comercio, el departamento denominado de Agricultura y Comercio en esta Constitución, se llamará Departamento de Agricultura.

Sección 9. — La primera elección bajo las disposiciones de esta Constitución se celebrará en la fecha que se disponga por ley, pero no más tarde de seis meses después de la fecha en que comience a regir esta Constitución y la siguiente se celebrará en el mes de noviembre de 1956, en el día que se determine por ley.

Sección 10. — Esta Constitución comenzará a regir cuando el Gobernador así lo proclame, pero no más tarde de sesenta días después de su ratificación por el Congreso de los Estados Unidos.

Dada en Convención reunida en el Capitolio de Puerto Rico el día seis de febrero del año de Nuestro Señor de mil novecientos cincuenta y dos.

GOBIERNO DE PUERTO RICO
Departamento de Salud

COMUNICADO DE PRENSA

3 de febrero de 2020

Salud advierte que el contagio por influenza es mayor que el de coronavirus

(San Juan, Puerto Rico) - Aunque el tema de salud pública que más ha acaparado la atención a nivel internacional es el novel Coronavirus (2019-nCoV), lo cierto es que la influenza sigue representando un riesgo mayor de contagio y hasta de muerte.

Frente a esta realidad, el secretario de Salud, doctor Rafael Rodríguez Mercado hizo un llamado a la ciudadanía a que se vacunen y observen las medidas básicas de higiene para evitar el contagio y propagación del virus.

Hasta ahora, el coronavirus ha infectado al menos 11 personas en los Estados Unidos, según datos de los Centros para el Control y la Prevención de Enfermedades, CDC, por sus siglas en inglés. Sin embargo, la influenza ha estado infectando a millones de estadounidenses. Tan es así que es más probable el contagio por influenza que el coronavirus. Los CDC estiman que, desde el 1 de octubre de 2019 hasta el 25 de enero de 2020, ha habido sobre:

- 19,000,000 contagios por influenza.
- 180,000 hospitalizaciones por influenza
- 8,600,000 consultas médicas por casos de influenza
- 10,000 muertes causadas por influenza

Según la Organización Mundial de la Salud, las epidemias de influenza estacional en todo el mundo causan entre 3 y 5 millones de casos graves cada año y matan hasta 650,000 personas al año. Estos datos, superan por mucho la cantidad de casos cuando se compara con el nuevo coronavirus. Por lo cual, tomando en consideración esos datos, podríamos considerar que si una persona no viajó a Wuhan, China o si no tuvo contacto con una persona con coronavirus, o sospechosa de tener el virus, la probabilidad de contraer este virus es relativamente baja.

"Al igual que el nuevo coronavirus, la influenza puede transmitirse de persona a persona a través del aire; pero hasta el momento el coronavirus no ha provocado ninguna muerte en los Estados Unidos. Sin embargo, la influenza le ha costado la vida a aproximadamente 10,000 estadounidenses desde octubre, según los datos ofrecidos por los CDC. La vacunación es el paso principal para prevenir la influenza. Las personas que reciben la vacuna adquieren inmunidad a enfermedades causadas por una bacteria o virus, lo cual también ayuda a proteger a las personas

Sin evidencia médica ni clínica el Departamento de Salud para sostener un estado de emergencia por epidemia en Puerto Rico

Y SI NO HAY EMERGENCIA, ¿POR QUÉ EXPONER A NUESTRA GENTE A UNA VACUNA EXPERIMENTAL? ¿POR QUÉ LAS RESTRICCIONES?

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Por: Jesús Rodríguez García

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El Departamento de Salud (DS) del Gobierno de Puerto Rico, al 18 de febrero de 2021, no cuenta con datos médico-clínicos para informarle a la población la cantidad de pacientes que han sido diagnosticados por médicos con la supuesta enfermedad denominada covid-19.

De igual forma, no conocen «el detalle del aspecto médico-clínico sobre la cantidad de pacientes que han sido diagnosticados utilizando únicamente los resultados de las pruebas rt-PCR y que no visitaron un médico. El Departamento de Salud que cierra negocios y orienta al gobierno para que establezca restricciones al pueblo de sus libertades civiles le dice a Radio Acromática que: «*En el sistema de vigilancia no se pregunta por diagnóstico de COVID-19, más aún los investigadores de caso{s} y los epidemiólogos no diagnosticamos a pacientes. Esta información no la podemos proveer*«. Entonces, ¿cómo llegan a la conclusión que en el país existe una emergencia? ¿La emergencia es de supuestos contagios y no de enfermos?

Más aún, el DS reconoce que la vigilancia de la publicitada epidemia es epidemiológica basada en resultados de pruebas de laboratorios realizadas y reportadas al Departamento de Salud, no es una vigilancia clínica.

La información que les estamos revelando la provee el propio DS, luego de que el juez Anthony Cuevas Ramos del Tribunal de Primera Instancia les instruyera para que cumplieran con la Ley 141 de 2019 conocida como «Ley de Transparencia y Procedimiento Expedito para Acceso a la Información Pública».

En octubre de 2020 le preguntamos a Lorenzo González, secretario de Salud de entonces, que del total de casos positivos «confirmados» ¿cuántos realmente estaban enfermos? González, un tanto sorprendido por la pregunta, entre unos cuantos titubeos contestó que no tenía esa información a la mano, pero que podrían conseguirla.

Luego de dos meses en espera para que proveyera la información nos dispusimos a escribirles formalmente el 17 de diciembre de 2020, para solicitarle datos puntuales sobre la supuesta emergencia que se supone estaba viviendo el país para esos días. Específicamente le enviamos por escrito 21 preguntas.

Ante la indiferencia a nuestra solicitud, junto al licenciado Adrián Díaz demandamos al DS para que entregaran la información pública con la que estaban sustentando una emergencia que ha provocado el cierre de miles de pequeños y medianos negocios, millones de dólares en pérdidas, miles de padres de familias desempleados, el cierre de nuestras escuelas y la imposición de órdenes ejecutivas completamente represivas y violatorias de los derechos constitucionales del Pueblo.

En una emergencia sustentada en la proliferación de casos positivos a las pruebas rt-PCR, el Departamento de Salud del Gobierno de Puerto Rico, no supervisa ni controla los estándares de precisión de dichas pruebas realizadas por los laboratorios privados. A pesar que las propias guías de los equipos utilizados establecen que deben hacerse a menos de 40 ciclos, durante toda esta supuesta epidemia, los laboratorios en Puerto Rico las hacen a 40 ciclos. De hecho, tenemos confirmación de varios médicos que llamaron a laboratorios donde estos así lo informaron.

Kary Mullis, quien inventó la reacción en cadena de la polimerasa (PCR), un método para amplificar o producir muchas copias de un fragmento específico de ADN, estableció que la prueba de diagnóstico ideal para las enfermedades infecciosas respiratorias deben tener alta sensibilidad y especificidad, alto valor predictivo, positivo y negativo. Según los entendidos, eso solo se logra si se analiza la pruebas a 25 ciclos o menos.

Tan temprano como el 6 de marzo de 2020, antes que el llamado virus llegara a la isla, la científica y doctora puertorriqueña Sally Priester Sepúlveda, convocó lo que podría considerarse la primera conferencia en todos los Estados Unidos que de manera preventiva, se discutió las maneras de cómo manejar el amenazante «virus». En dicha conferencia celebrada en el hotel AC Marriott del Condado, había personal del DS y Priester Sepúlveda junto a otro experto que llegó desde Texas invitado por esta, advirtieron que las pruebas PCR no eran apropiadas para detectar los viruses.

De otra parte, en una entrevista transmitida por la Cadena Wapa Radio, la Dra. Roxana Bruno, licenciada en bioquímica y doctora en inmunología, con posdoctorados en el Instituto Max Planck de Neurobiología de Alemania y en el Instituto de Neurociencias de Alicante, en España, ofreció una explicación fácil de comprender sobre las pruebas PCR o moleculares.

"Lo primero y más importante que tenemos que tener en cuenta en esta pandemia, es que no hemos podido verificar que existan aislamientos satisfactorios del virus sars cov 2.

Es decir, desde el comienzo todos los procedimientos que se hicieron en esta pandemia desde que se inició en China han sido incompletos. Nunca han sido aislamientos del virus satisfactorios a partir de los pacientes. China ha proporcionado secuencias genéticas de virus y también muchos países lo han secuenciado.

Pero no se dispone de aislamiento cuantificado del virus que lo podamos ver aislado a partir de muestras respiratorias. El diagnóstico de esa enfermedad se realiza entonces a partir de un test que es para detectar la presencia del nuevo virus en las vías respiratorias. Mediante la reacción que se llama PCR o reacción en cadena de la Polimerasa.

¿Qué tiene este test? Que si bien ha sido recomendado por la Organización Panamericana de la Salud y la Organización Mundial de la Salud, es curioso que este test se diseñó en ausencia del virus de los pacientes incluso de Wuhan. Y ellos mismos, los creadores del test afirman que este método se diseñó en ausencia del virus y por lo tanto significa que se realizó utilizando ácido nucleico sintético.

Es decir, virus sintetizados de manera artificial en el laboratorio. Por lo tanto, una prueba que se detecta o se informa como positiva, nunca se correlacionó con un cultivo de virus viable, porque no fue un cultivo cuantificado del virus.

Entonces, una prueba PCR positiva, indica infectividad. No indica que la persona tenga virus infectivos en sus vías respiratorias. No significa la presencia de partícula viral. Sino, que puede ser simplemente un coronavirus que es agente endémico causal del resfrío común.

Además, también se ha visto que puede ser que haya reacción cruzada, es decir, que dé positivo con cualquier otro agente que esté en las vías respiratorias.

Entonces, esto es sentido común. Ustedes fíjense: ¿Cuántos en el mundo han tenido un PCR positivo pero nunca se han enfermado? Porque esta prueba, aparentemente detecta coronavirus en los individuos sanos que no desarrollan nunca un síntoma y también en algunos enfermos que tienen neumonía o alguna patología respiratoria.

Entonces, ¿cómo puede ser que de positivo en sanos y de positivo en enfermos?

¿Se puede decir que este es el agente infeccioso el sars cov 2, el que está causando la enfermedad? La respuesta es NO.

Porque las pruebas no son específicas para sars cov 2. Entonces, se puede estar detectando otros coronavirus del resfrío u otros virus que causan problemas respiratorios u otros genes codificados por el propio genoma humano.

Es lo que han alertado autoridades sanitarias de varios países del mundo. Que han desaconsejado el uso masivo de estos test, porque hay mucha inespecificidad. Hay grandes cantidades de lo que se llama positivos falsos. Que da positivo, pero la persona no está enferma. Y por lo tanto, si da como positivo a alguien que no está enfermo, los datos de la transmisión de la enfermedad y de los contagios no son reales. La enfermedad, la verdadera situación sanitaria no es la que dicen los test", concluyó.

Obviamente, las cientos de miles de pruebas hechas en Puerto Rico, en su gran mayoría deberían estar bajo la seria sospecha de que son falsos positivos por su falta de confiabilidad. Dado que no se siguieron los estándares adecuados para lograr la obtención de una muestra de mayor precisión. El mismo Anthony Fauci, que muchos tienen como especialista en enfermedades infecciosas, pero de dudosa reputación ha dicho que todo lo que arrojen las PCR, por encima de los 35 ciclos es pura basura.

El DS se ha cantado ajeno y desconocedor de los protocolos seguidos por los laboratorios privados para la ejecución de las pruebas. Sin embargo, utiliza la información que estos proveen para establecer política pública relacionada a la llamada pandemia, sin establecer controles de calidad y precisión. Es precisamente el DS quien se supone autoriza y regula a los laboratorios clínicos y sus protocolos a seguir.

Lo anterior, parece indicar que todos los involucrados fallaron en desconocer los protocolos y las técnicas de las PCR. Lo que seguramente elevó artificialmente las estadísticas de casos positivos, en su gran mayoría personas que nunca se enfermaron. «Falsos positivos» por la manera erráticas en que se realizan las pruebas.

El dudoso manejo de estas, le ha costado al pueblo de Puerto Rico dolor y sacrificio. Durante todo un año viviendo el terror de contagiarse con un virus que, de no ser por el alto número de falsos positivos, no tendrías por qué vivir con tanto miedo. Deberíamos dejar el miedo a un lado y meditar si realmente han sido necesarias tantas restricciones.

Cabe señalar que las PCR, es el principal argumento en las demandas internacionales en la Corte de la Haya, lideradas por el **licenciado Reiner Fuelmich**. Este asegura que las pruebas no detectan el supuesto covid-19 por lo que la llamada pandemia es un fraude.

Los virus siempre han convivido con nosotros y los médicos los tratan atendiendo signos y síntomas. No obstante se han etiquetado decenas de miles de personas como enfermas de covid, sin que un médico los examine y los diagnostique. **O todos han pecado de ignorantes e incompetentes, o todos sabían de la «Plandemia». ¿Generaron la ola de falsos positivos para sembrar el pánico y justificar las vacunas?**

Aunque en un principio por recomendaciones de la Organización Mundial de la Salud (OMS), no se habían estado realizando autopsias a los fallecidos por covid, a preguntas nuestras, Salud incluye datos provistos por el Instituto de Medicina Forense. Nos dice que de 100 personas muertas con diagnóstico covid, han realizado 47 autopsias. De estas, treinta (30) casos tienen causa de muerte no relacionada a covid 19. Cuatro (4) casos la causa de muerte fue o está relacionada con Covid 19 y una (1) de manera «contributoria». Doce (12) casos están pendiente de estudio.

Al hacer el cálculo matemático en relación a las 35 autopsias ya estudiadas, con un resultado de 30 no covid y 5 relacionadas al supuesto y siguiendo esa tendencia, podríamos estimar que hasta el 22 de marzo de 2021, de las 2,060 muertes que Salud le atribuye al susodicho, 1,899 tuvieron causas de muertes ajenas al diagnóstico covidiano, mientras solo 161 pudieron haber fallecido a consecuencia de eso que llaman covid-19. Es importante preguntarnos, ¿cómo llegaron a esa conclusión si el Sars-cov-2 no ha sido identificado mediante aislamiento y purificación. Tampoco micrografiado.

Como son muchas las preguntas, les comparto el documento íntegro para que lo lean por ustedes mismos y lleguen a sus propias conclusiones. Nótese como la constante es el desconocimiento, la falta de datos y detalles empíricos.

Vea la solicitud de información:

Lea la demanda:

GOBIERNO DE PUERTO RICO
Departamento de Justicia

Hon. Pedro R. Pierluisi Urrutia
Gobernador
Hon. Domingo Emanuelli Hernández
Secretario de Justicia Designado

A: **Lcdo. Adrián Diaz**
Representante legal de Parte Peticionaria

De: *f/Ada Sánchez Torres*
Lcda. Ada Sánchez Torres
Abogada
División Recursos Extraordinarios
Departamento de Justicia

Fecha: **18 de febrero de 2021**

Asunto: **Desglose de respuestas del Departamento de Salud a las preguntas realizadas por la parte demandante en el caso Rodríguez García V. Departamento de Salud, SJ2021CV00446**

1. *¿Qué cantidad de pacientes han sido diagnosticados con la enfermedad COVID 19 por médicos en Puerto Rico?*

   Respuesta del Departamento de Salud : El Departamento de Salud no cuenta con el detalle de la información solicitada. Los datos que posee el Departamento de Salud están sustentados por un sistema de vigilancia epidemiológica basado en resultados de pruebas de laboratorios realizadas y reportadas al Departamento de Salud. No es una vigilancia clínica. Por consiguiente, no contamos con el detalle del aspecto médico-clínico.

2. *¿Qué cantidad de pacientes han sido diagnosticados con la enfermedad COVID-19 utilizando únicamente los resultados de las pruebas rt-PCR? ¿Que no visitaron a un médico?*

   Respuesta del Departamento de Salud : El Departamento de Salud no cuenta con el detalle de la información solicitada. Los datos que posee el Departamento de Salud están sustentados por un sistema de vigilancia epidemiológica basado en resultados de pruebas de laboratorios realizadas y reportadas al Departamento de Salud. No es una vigilancia clínica. Por consiguiente, no contamos con el detalle del aspecto médico-clínico.

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OBJECION - Se solicita se aclare la respuesta toda vez que en la contestación #5 indica el número de prueba de rt-PCR que han realizado, por lo que se entiende el Departamento debería informar cuantos de esos resultados los ha utilizado como incluidos en casos positivos a COVID-19.

Respuesta del Departamento de Salud: La pregunta se basa en pacientes diagnosticados solamente con pruebas RT PCR que no fueron a médicos. En el sistema de vigilancia no se pregunta por diagnóstico de COVID-19, más aún los investigadores de caso y los epidemiólogos no diagnosticamos a pacientes. Esta información no la podemos proveer.

3. ***¿Qué cantidad de pacientes han sido diagnosticados con la enfermedad de COVI-19 por un médico en Puerto Rico y que haya tenido un resultado positivo a la prueba rt-PCR y qué síntomas mostraron?***

   Respuesta del Departamento de Salud : El Departamento de Salud no cuenta con el detalle de la información solicitada. Los datos que posee el Departamento de Salud están sustentados por un sistema de vigilancia epidemiológica basado en resultados de pruebas de laboratorios realizadas y reportadas al Departamento de Salud. No es una vigilancia clínica. Por consiguiente, no contamos con el detalle del aspecto médico-clínico.

4. ***¿Qué cantidad de pacientes han sido diagnosticados con la enfermedad de COVID-19 utilizando el resultado positivo de la prueba rt-PCR, que fueran a su vez atendidos por un médico y que no tuvieron síntomas de la enfermedad?***

   Respuesta del Departamento de Salud : El Departamento de Salud no cuenta con el detalle de la información solicitada. Los datos que posee el Departamento de Salud están sustentados por un sistema de vigilancia epidemiológica basado en resultados de pruebas de laboratorios realizadas y reportadas al Departamento de Salud. No es una vigilancia clínica. Por consiguiente, no contamos con el detalle del aspecto médico-clínico.

5. ***¿Qué cantidad de pruebas de rt-PCR ha realizado el Depto. de Salud durante el año 2020?***

   Respuesta del Departamento de Salud :Durante el transcurso del año 2020 el Instituto del Laboratorio de Salud Pública del Departamento de Salud realizó un total de **143,549** pruebas de RT-PCR.

6. ***Provea copia de todo documento o protocolo preparado por el Departamento de Salud de Puerto Rico, o aquel documento que se esté utilizando para establecer la***

forma de colectar las muestras de los pacientes para ser analizadas mediante las pruebas de rt-PCR.

Se acompaña documento provisto por el Departamento de Salud: *Protocolo Manejo Muestras COVID 19.*

7. ***Provea copia de todo documento o protocolo preparado por el Departamento de Salud de Puerto Rico, o aquel documento que se esté utilizando para establecer la forma en que se analizan las muestras de los pacientes mediante las pruebas de rt-PCR.***

   Se acompaña documento provisto por el Departamento de Salud: *Guías del CDC– CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.*

8. ***Provea copia de todo contrato o acuerdo que tenga el Departamento de Salud con laboratorios privados para la realización de las pruebas rt-PCR en Puerto Rico.***

   Se acompañan documentos provistos por el Departamento de Salud (son 4 pdf)

9. ***Indique qué cantidad de ciclos de replicación de material genérico se están utilizando en las pruebas de rt-PCR para obtener las lecturas por los laboratorios y técnicos del Departamento de Salud.***

   Respuesta del Departamento de Salud : El Departamento de Salud se está dejando llevar para la realización de todo el proceso por las guías anteriormente suministradas. Véase, *Guías del CDC– CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.*

   > OBJECION – Al revisar las Guías, a la pág. 37 de las mismas se desprende el uso de un "threshold cycle" de 40. Por lo que se solicita al Departamento que verifique su contestación o pueda corroborar el Dato.
   >
   > *Respuesta del Departamento de Salud: Las Guías del CDC– CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, las cuales utiliza el Departamento de Salud para el diagnóstico de CoVID-19, establecen que para considerar un paciente positivo su muestra debe presentar una curva de crecimiento en N1 y N2 menor de 40(Ct <40.00)*

10. ***Indique qué cantidad de ciclos de replicación de material genético se está utilizando en las pruebas de rt-PCR para obtener las lecturas por los laboratorios privados que reportan sus resultados al Departamento de Salud.***

Respuesta del Departamento de Salud : Conforme a la metodología que utiliza cada laboratorio vienen obligados a seguir las indicaciones establecidas por el manufacturero a esos efectos.

> OBJECION – Al revisar las Guías, a la pág. 37 de las mismas se desprende el uso de un "threshold cycle" de 40 . Por lo que se solicita al Departamento que verifique su contestación o pueda corroborar el Dato. El peticionario tiene confirmación de dos galenos que llamaron a laboratorios y les indicaron que usaban 40 ciclos para detección de las muestras.
>
> ***Respuesta del Departamento de Salud**: El Departamento de Salud se encuentra impedido de proveer la información específica de cada método implementado en los laboratorios. Esta información deberá ser provista por los laboratorios privados. No es información que forme parte de la recopilación de datos del Departamento de Salud, por lo que no se encuentra en nuestro poder. Nuestra contestación anterior se encuentra dirigida a las recomendaciones realizadas por los manufactureros de los equipos.*

11. ***Indique cuántos resultados positivos a pruebas rt-PCR se han reportado utilizando una cantidad de replicación de material genético mayor a los 35 ciclos de replicación.***

Respuesta del Departamento de Salud : Conforme a los procesos de reporte establecido en el Instituto de Laboratorio de Salud Pública, avalado por las regulaciones estatales y federales, se emite el resultado de forma cualitativa.

> OBJECION – Al revisar las Guías, a la pág. 37 de las mismas se desprende el uso de un "threshold cycle" de 40. Por lo que se solicita al Departamento que verifique su contestación o pueda corroborar el Dato. El peticionario tiene confirmación de dos galenos que llamaron a laboratorios y les indicaron que usaban 40 ciclos para detección de las muestras.
>
> ***Respuesta del Departamento de Salud**: El valor del Ct obtenido no forma parte del reporte de resultados utilizado por el Departamento de Salud. Este valor se recolecta solo como parte de la data cruda y es utilizado para la interpretación final de resultados.*

12. ***¿Cuántos cultivos virus a pacientes diagnosticados con la enfermedad COVID-19 se han hecho?***

Respuesta del Departamento de Salud : En el Instituto de Laboratorios de Salud Pública no se realizan cultivos de virus a pacientes. Conforme a los procedimientos y las guías de los CDC no se establece el llevar a cabo un cultivo de virus para estos efectos.

13. ***¿Cuántas autopsias se han hecho a pacientes que se alega han fallecido con un diagnóstico de COVID-19?***

Respuesta del Departamento de Salud : Esta información no la tiene el Departamento de Salud pues no es parte de nuestros servicios. Quien debe tener la información solicitada es el Instituto Ciencias Forenses.

Respuesta del Instituto de Ciencias Forenses : Hasta este momento, se han realizado 100 exámenes externos, de los cuales 92 casos presentan del diagnóstico de Covid 19 entre las causas de muerte y 8 casos presentan el diagnóstico de Covid 19 de manera contributoria. Hasta este momento, se han realizado 47 autopsias a casos que arrojaron positivo a Covid 19 que se desglosan de la a siguiente manera:

a. 5 casos, 4 de los cuales, la causa de muerte es o está relacionada con Covid 19 y 1 de ellas de manera contributoria.
b. 30 casos que tienen causa de muerte no relacionada a Covid 19.
c. 12 casos que están pendientes de estudio.

14. ***¿Indique qué equipos utiliza el Departamento de Salud para hacer las pruebas rt-PCR?***

Respuesta del Departamento de Salud :

MagNA Pure : https://lifescience.roche.com/global_en/brands/magnapure.html#magna-pure-96
MagNa Pure LC
MAgNA Pure 96

Applied Biosystems Real-Time PCR Instruments
ABI 7500Fast DX: https://www.thermofisher.com/pr/en/home/life-science/pcr/real-time-pcr/real-time-pcr-instruments/7500-fast-real-time-pcr-system.html

QuantStudio DX : https://www.thermofisher.com/pr/en/home/clinical/diagnostic-testing/instruments-automation/genetic-analysis-instruments/quantstudio-dx-real-time-pcr-instrument.html

Prueba: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel
Equipo de Extracción –
1. MagnaPure 96,
2. MagnaPure LC
3. EZ1 Advanced XL

Equipo de Amplificacion –
1. ABI7500 DX
2. Quantstudio DX

Prueba: Xpert® Xpress SARS-CoV-2
Equipo - GeneXpert Dx

15. *Indique que compañía ha contratado el Departamento de Salud para que suministre los reactivos para las pruebas de rt-PCR para material genético del COV-SARS-2.*

    Respuesta del Departamento de Salud: Todos los reactivos que se utilizaron en el periodo de tiempo requerido fueron provistos por el Departamento de Salud Federal a través del CDC. Durante el periodo de tiempo requerido, los reactivos para la prueba de **CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel** fueron provistos sin costo por el Departamento de Salud Federal a través del CDC. Los reactivos para la prueba **Xpert® Xpress SARS-CoV-2** fueron adquiridos mediante orden de compra.
    Se acompañan documentos provistos por el Departamento de Salud (son 4 pdf)

16. *Provea copia del manual de uso, mantenimiento y calibración de los equipos utilizados para las pruebas de rt-PCR para material genético del COV-SARS-2.*

    Respuesta del Departamento de Salud : Refiérase a la contestación del inciso 14, donde se copian los enlaces relacionados a los equipos. Del mismo modo encontrarán copia de los manuales de mantenimiento de los mismos.

17. *¿Quiénes son las personas que en el Depto. de Salud certifica si en efecto un paciente murió por COVID-19?*

    Respuesta del Departamento de Salud : Conforme a la reglamentación vigente en Puerto Rico, es un médico licenciado quien está autorizado a emitir una certificación de muerte y las causas. El Departamento de Salud no hace esta tarea.

18. *¿Cuántas personas en Puerto Rico ha sido diagnosticados con la enfermedad de COVID 19 y no han sido hospitalizadas?*

Respuesta del Departamento de Salud : No se cuenta con el detalle de la información. Los datos que posee el Departamento de Salud están sustentados por un sistema de vigilancia epidemiológica basado en resultados de pruebas de laboratorios realizadas y reportadas al Departamento de Salud. No es una vigilancia clínica. Por consiguiente, el Departamento de Salud no cuenta con el detalle del aspecto médico-clínico.

Para poder tener una idea, se recomienda la verificación del *Dashboard,* en la página web de la agencia, donde se reportan la cantidad de casos positivos y la cantidad de personas que se encuentran en intensivo con relación al COVDI-19.

19. ***¿Cuántos pacientes diagnosticados con la enfermedad de Covid 19 se han recuperado?***

    Respuesta del Departamento de Salud : De acuerdo con la información reportada a través del *Dashboard* COVID-19 del Departamento de Salud, al 31 de diciembre del 2020 el total de pacientes convalecientes era 66,113.

20. ***¿Cuántas personas han sido hospitalizadas con diagnósticos con COVID-19 y que tengan diagnosticadas otras comorbilidades?***

    Respuesta del Departamento de Salud : El Departamento de Salud no cuenta con el detalle de la información. Los datos que posee el Departamento de Salud están sustentados por un sistema de vigilancia epidemiológica basado en resultados de pruebas de laboratorios realizadas y reportadas al Departamento de Salud. El Sistema de Vigilancia no es una vigilancia clínica. El Sistema de Vigilancia no recopila datos sobre comorbilidades diagnosticadas por médicos; se basa en el auto reporte del dato por parte de los casos o sus proxys. Por consiguiente, el Departamento de Salud no cuenta con este detalle del aspecto médico-clínico.

21. ***¿En qué consiste la clasificación "casos probables" a la enfermedad de COVID-19?***

    Respuesta del Departamento de Salud : Las definiciones de casos de COVID-19 provienen de la definición establecida por el CSTE. El CSTE actualizó las definiciones de caso el 4 de agosto del 2020, y a partir de esa fecha se clasifican los casos probables como aquellos que cumplan con una de las siguientes categorías:

    - Caso que cumpla con criterios clínicos y tenga un vínculo epidemiológico sin tener prueba confirmatoria de laboratorio para SARS-CoV-2.
    - Caso que cumpla con una prueba positiva de antígeno

- Caso que cumpla con el criterio de registros vitales sin tener prueba confirmatoria de SARS-CoV-2.

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Población: Población
Población: Densidad de población
Población: Tasa de crecimiento
Población: Tasa de natalidad
Población: Tasa de mortalidad

Afganistán
Akrotiri
Albania
Alemania
Andorra

Submit

Tasa de mortalidad (muertes/1000 habitantes)

20002001200220032004200520062007200820092010201120122013201420152016201720182019202067891011AñoMundo

Country	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2011	2012	2013	2014	2016	2018	2020
Mundo	9	8,93	8,93	8,83	8,86	8,78	8,67	8,37	8,23	8,37	8,12	7,99	7,9	7,89	7,7	7,7	7,7

Definición de Tasa de mortalidad: Esta entrada proporciona el promedio anual de muertes durante un año por cada 1,000 habitantes a mediados de año; también conocido como tasa de mortalidad cruda. La tasa de mortalidad, si bien solo es un indicador aproximado de la situación de la mortalidad en un país, indica con precisión el impacto de la mortalidad actual sobre el crecimiento de la población. Este indicador se ve significativamente afectado por la distribución por edad, y la mayoría de los países finalmente mostrarán un aumento en la tasa de mortalidad general, a pesar del descenso continuo de la mortalidad en todas las edades, ya que la disminución de la fertilidad da como resultado una población que envejece.

Fuente: CIA World Factbook - A menos que sea indicado, toda la información en esta página es correcta hasta Diciembre 1, 2020

https://www.indexmundi.com/g/g.aspx?c=xx&v=26&l=es

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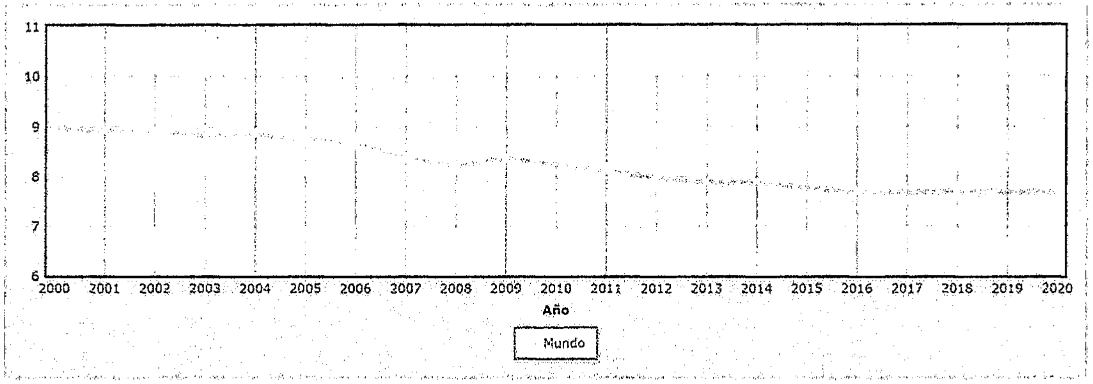
Población: Tasa de natalidad
Población: Tasa de mortalidad

Mongolia
Montenegro
Montserrat
Mozambique
Mundo

Submit

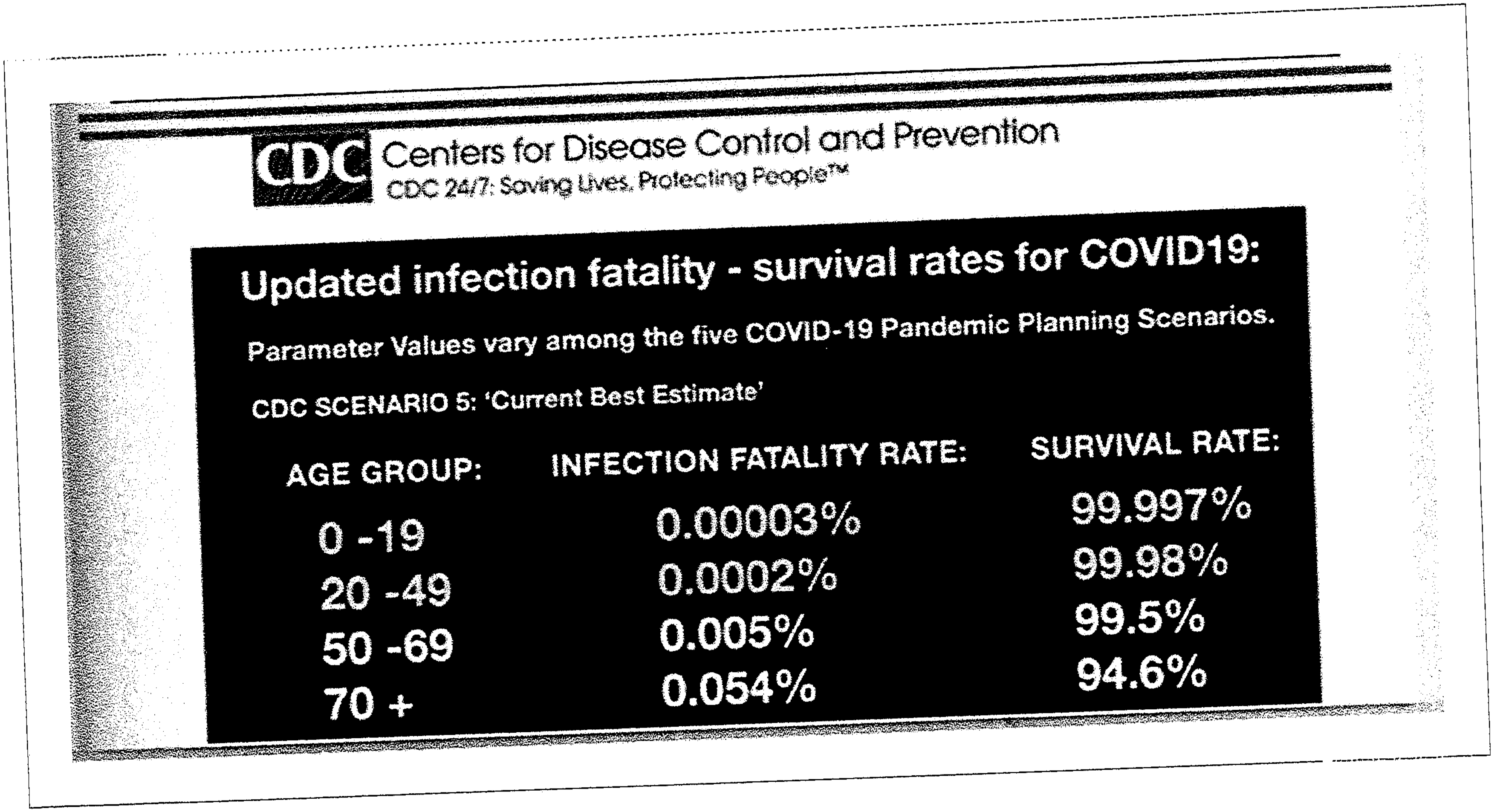
Tasa de mortalidad (muertes/1000 habitantes)



Me gusta 2,8 mil

Country	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2011	2012	2013	2014	2016	2018	2020
Mundo	9	8,93	8,93	8,83	8,86	8,78	8,67	8,37	8,23	8,37	8,12	7,99	7,9	7,89	7,7	7,7	7,7

Definición de Tasa de mortalidad: Esta entrada proporciona el promedio anual de muertes durante un año por cada 1,000 habitantes a mediados de año; también conocido como tasa de mortalidad cruda. La tasa de mortalidad, si bien solo es un indicador aproximado de la situación de la mortalidad en un país, indica con precisión el impacto de la mortalidad actual sobre el crecimiento de la población. Este indicador se ve significativamente afectado por la distribución por edad, y la mayoría de los países finalmente mostrarán un aumento en la tasa de mortalidad general, a pesar del descenso continuo de la mortalidad en todas las edades, ya que la disminución de la fertilidad da como resultado una población que envejece.



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Updated infection fatality - survival rates for COVID19:

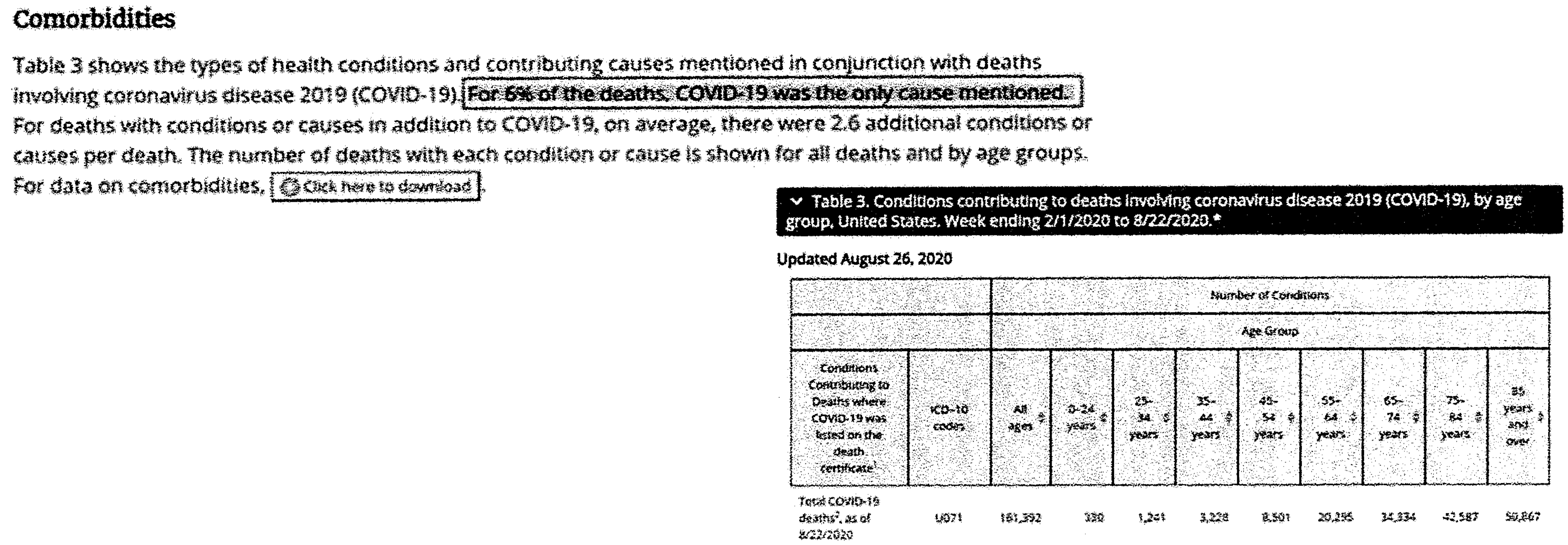
Parameter Values vary among the five COVID-19 Pandemic Planning Scenarios.

CDC SCENARIO 5: 'Current Best Estimate'

AGE GROUP:	INFECTION FATALITY RATE:	SURVIVAL RATE:
0 -19	0.00003%	99.997%
20 -49	0.0002%	99.98%
50 -69	0.005%	99.5%
70 +	0.054%	94.6%

40

This week the CDC quietly updated the Covid number to admit that only 6% of all the 161,392 deaths recorded actually died solely from Covid.



Comorbidities

Table 3 shows the types of health conditions and contributing causes mentioned in conjunction with deaths involving coronavirus disease 2019 (COVID-19). For 6% of the deaths, COVID-19 was the only cause mentioned. For deaths with conditions or causes in addition to COVID-19, on average, there were 2.6 additional conditions or causes per death. The number of deaths with each condition or cause is shown for all deaths and by age groups. For data on comorbidities, Click here to download.

Table 3. Conditions contributing to deaths involving coronavirus disease 2019 (COVID-19), by age group, United States. Week ending 2/1/2020 to 8/22/2020.*

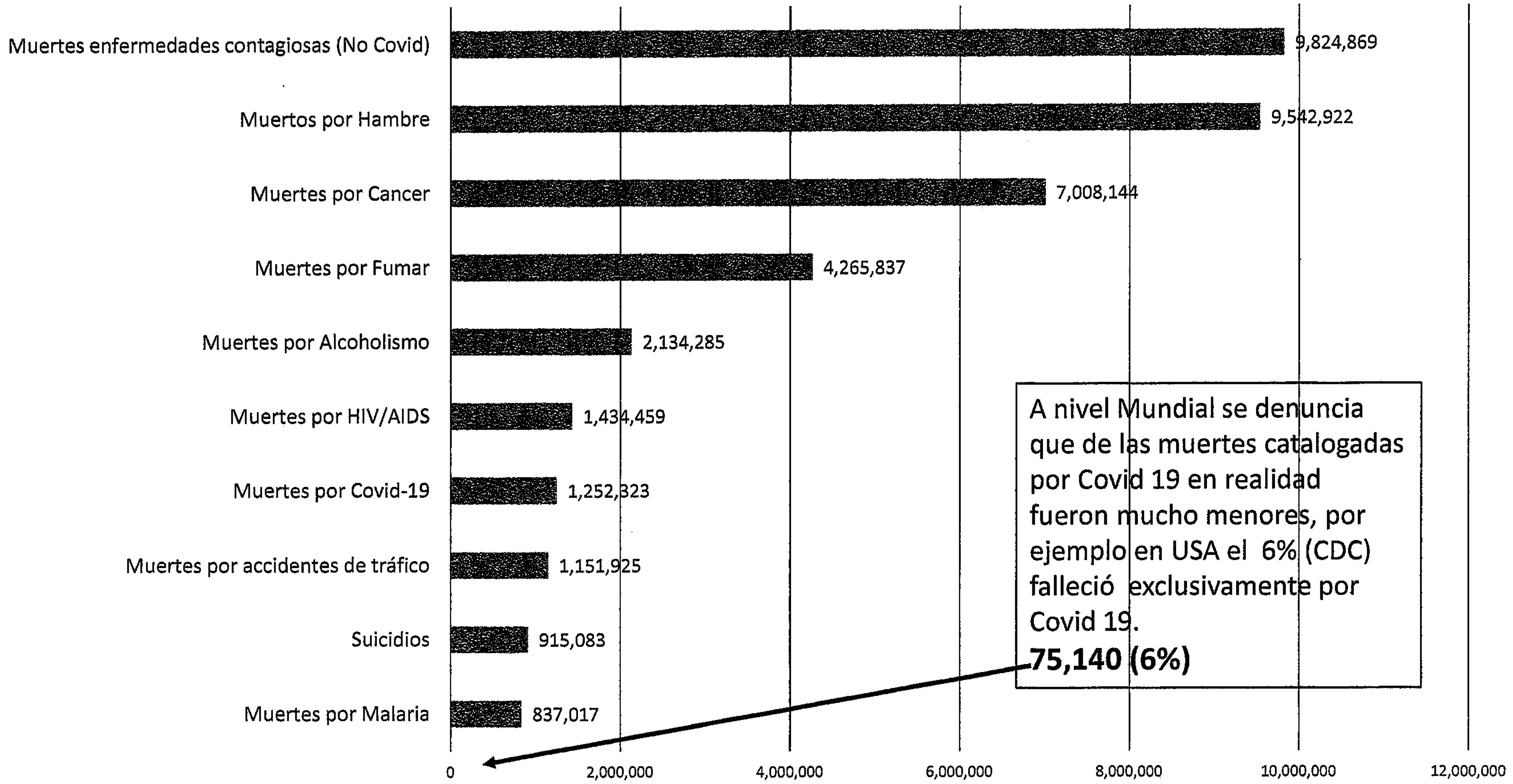
Updated August 26, 2020

		Number of Conditions								
		Age Group								
Conditions Contributing to Deaths where COVID-19 was listed on the death certificate[1]	ICD-10 codes	All ages	0-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85 years and over
Total COVID-19 deaths[2], as of 8/22/2020	U071	161,392	330	1,241	3,228	8,501	20,295	34,334	42,587	50,867

Source: https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR2PcFrRYmWibcz886GrQnZPmJqSswsIV9mXkhTkip14YaTRC-8qSfGLxpw

Datos Mundiales de Muertes

Nov 7 2020 11:30am https://www.worldometers.info/



A nivel Mundial se denuncia que de las muertes catalogadas por Covid 19 en realidad fueron mucho menores, por ejemplo en USA el 6% (CDC) falleció exclusivamente por Covid 19.

75,140 (6%)

Tabla 4.4: Tasas de mortalidad por grupos de edad en Puerto Rico, 2004-2013

CAUSA DE MUERTE	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Cáncer	4,846	4,865	4,832	4,989	5,008	5,089	5,197	5,286	5,439	5,219
Corazón	6,163	6,208	5,815	5,628	5,356	5,225	5,211	5,286	5,089	5,087
Diabetes	2,000	2,800	2,609	2,732	2,852	2,815	2,959	3,225	3,115	3,145
Alzheimer	1,170	1,402	1,269	1,577	1,591	1,600	1,863	1,838	2,018	1,828
Cerebrovasculares	1,639	1,540	1,574	1,654	1,529	1,459	1,504	1,515	1,362	1,352
Accidentes	1,202	1,213	1,249	1,214	1,097	1,025	1,031	1,110	1,023	1,045
Enf. Respiratorias	1,136	1,221	1,046	1,110	1,200	1,152	1,092	1,055	1,011	999
Nefritis	923	944	955	1,028	1,058	1,032	989	957	1,013	892
Homicidios	771	792	741	724	821	929	964	1,075	958	869
Septicemia	813	870	813	878	861	879	775	823	803	804
Neumonía e Influenza	1,058	1,087	963	1,023	949	1,022	821	841	788	752
Hipertensión	401	438	458	436	520	626	499	511	565	568
Suicidios[b]										242

Casos COVID-19 en Puerto Rico

CASOS CONFIRMADOS (RT-PCR+)	CASOS PROBABLES (Antígenos)	CASOS SOSPECHOSOS (Anticuerpos)	MUERTES
50,081	1,500	40,367	1,083

Datos al 28 de noviembre de 2020, del Laboratorio de Salud Pública del Departamento de Salud, Sistema de Salud de Veteranos del Caribe y laboratorios privados. Para información más detallada: Instituto de Estadísticas de Puerto Rico>>

World Health Organization

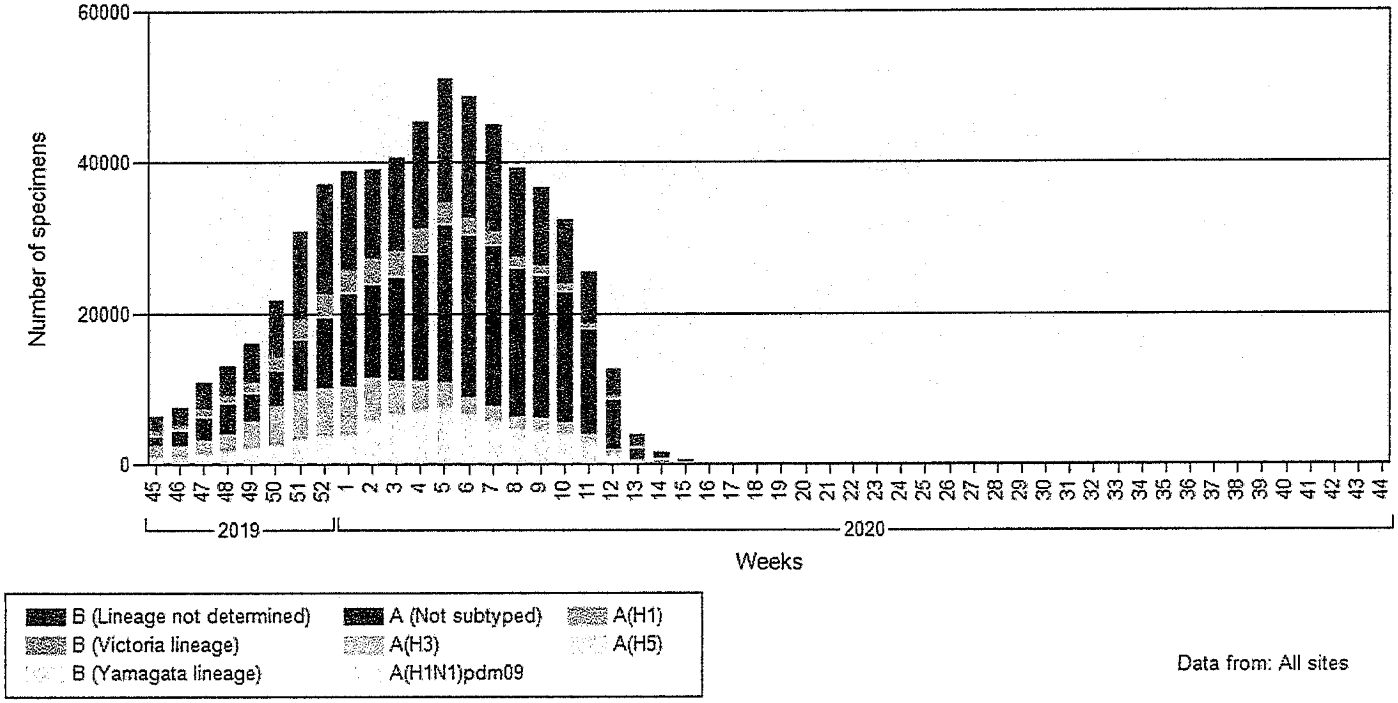
Influenza Laboratory Surveillance Information

by the Global Influenza Surveillance and Response System (GISRS)

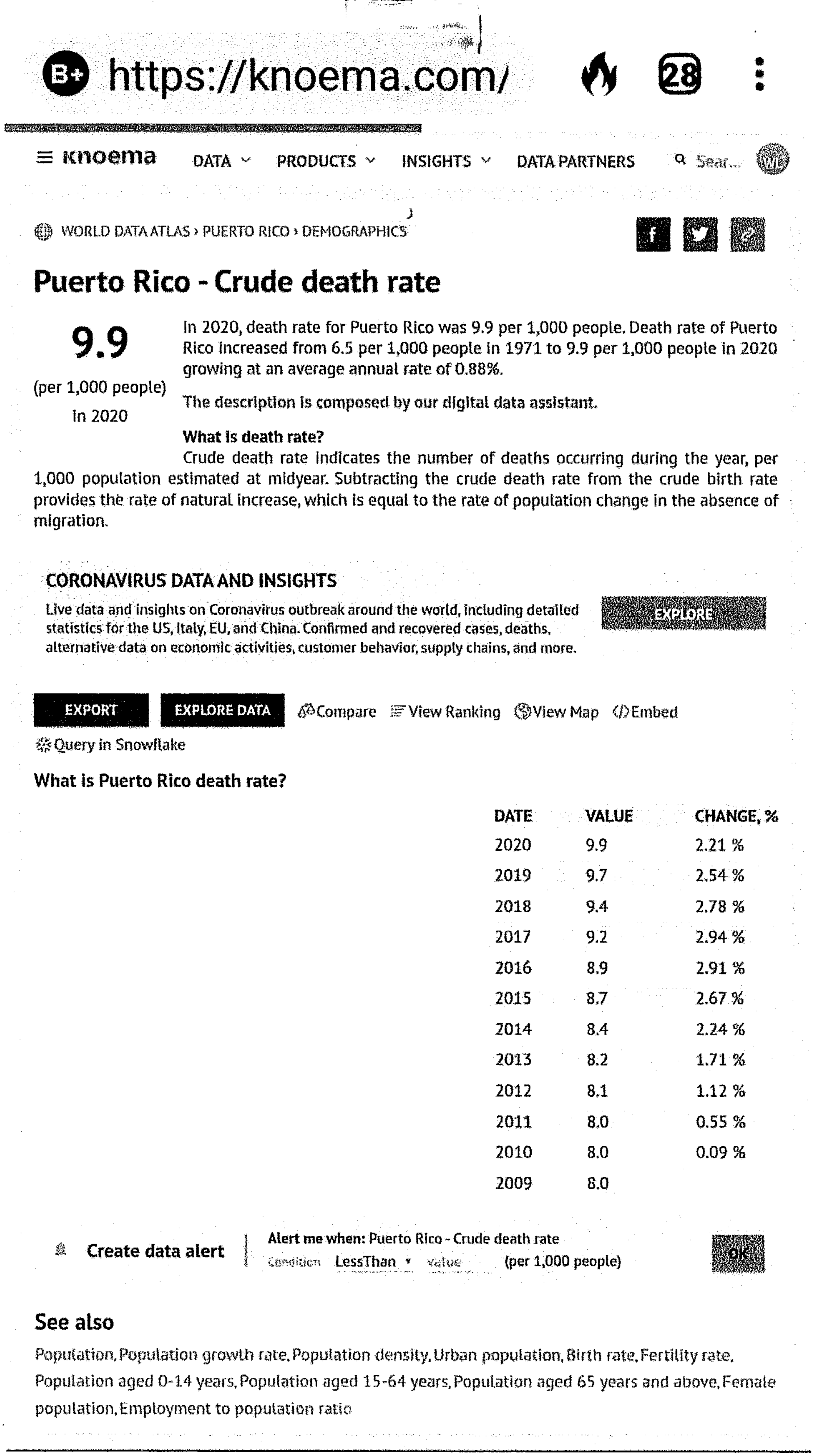
generated on 07/11/2020 16:46:37 UTC

Global circulation of influenza viruses

Number of specimens positive for influenza by subtype



Data from: All sites



WORLD DATA ATLAS › PUERTO RICO › DEMOGRAPHICS

Puerto Rico - Crude death rate

9.9

(per 1,000 people)
in 2020

In 2020, death rate for Puerto Rico was 9.9 per 1,000 people. Death rate of Puerto Rico increased from 6.5 per 1,000 people in 1971 to 9.9 per 1,000 people in 2020 growing at an average annual rate of 0.88%.

The description is composed by our digital data assistant.

What is death rate?

Crude death rate indicates the number of deaths occurring during the year, per 1,000 population estimated at midyear. Subtracting the crude death rate from the crude birth rate provides the rate of natural increase, which is equal to the rate of population change in the absence of migration.

CORONAVIRUS DATA AND INSIGHTS

Live data and insights on Coronavirus outbreak around the world, including detailed statistics for the US, Italy, EU, and China. Confirmed and recovered cases, deaths, alternative data on economic activities, customer behavior, supply chains, and more.

What is Puerto Rico death rate?

DATE	VALUE	CHANGE, %
2020	9.9	2.21 %
2019	9.7	2.54 %
2018	9.4	2.78 %
2017	9.2	2.94 %
2016	8.9	2.91 %
2015	8.7	2.67 %
2014	8.4	2.24 %
2013	8.2	1.71 %
2012	8.1	1.12 %
2011	8.0	0.55 %
2010	8.0	0.09 %
2009	8.0	

Create data alert

Alert me when: Puerto Rico - Crude death rate
Condition LessThan Value (per 1,000 people)

See also

Population, Population growth rate, Population density, Urban population, Birth rate, Fertility rate, Population aged 0-14 years, Population aged 15-64 years, Population aged 65 years and above, Female population, Employment to population ratio

DATE	VALUE	CHANGE, %
2020	9.9	2.21 %
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2013	8.2	1.71 %
2012	8.1	1.12 %
2011	8.0	0.55 %
2010	8.0	0.09 %
2009	8.0	

The Great Barrington Declaration

The Great Barrington Declaration – As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

Coming from both the left and right, and around the world, we have devoted our careers to protecting people. Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden. Keeping students out of school is a grave injustice.

Keeping these measures in place until a vaccine is available will cause irreparable damage, with the underprivileged disproportionately harmed.

Fortunately, our understanding of the virus is growing. We know that vulnerability to death from COVID-19 is more than a thousand-fold higher in the old and infirm than the young. Indeed, for children, COVID-19 is less dangerous than many other harms, including influenza.

As immunity builds in the population, the risk of infection to all – including the vulnerable – falls. We know that all populations will eventually reach herd immunity – i.e. the point at which the rate of new infections is stable – and that this can be assisted by (but is not dependent upon) a vaccine. Our goal should therefore be to minimize mortality and social harm until we reach herd immunity.

The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk. We call this Focused Protection.

Adopting measures to protect the vulnerable should be the central aim of public health responses to COVID-19. By way of example, nursing homes should use staff with acquired immunity and perform frequent testing of other staff and all visitors. Staff rotation should be minimized. Retired people living at home should have groceries and other essentials delivered to their home. When possible, they should meet family members outside rather than inside. A comprehensive and detailed list of measures, including approaches to multi-generational households, can be implemented, and is well within the scope and capability of public health professionals.

Those who are not vulnerable should immediately be allowed to resume life as normal. Simple hygiene measures, such as hand washing and staying home when sick should be practiced by everyone to reduce the herd immunity threshold. Schools and universities should be open for in-person teaching. Extracurricular activities, such as sports, should be resumed. Young low-risk adults should work normally, rather than from home. Restaurants and other businesses should open. Arts, music, sport and other cultural activities should resume. People who are more at risk may participate if they wish, while society as a whole enjoys the protection conferred upon the vulnerable by those who have built up herd immunity.

On October 4, 2020, this declaration was authored and signed in Great Barrington, United States, by:

Dr. Martin Kulldorff, professor of medicine at Harvard University, a biostatistician, and epidemiologist with expertise in detecting and monitoring infectious disease outbreaks and vaccine safety evaluations.

Dr. Sunetra Gupta, professor at Oxford University, an epidemiologist with expertise in immunology, vaccine development, and mathematical modeling of infectious diseases.

Dr. Jay Bhattacharya, professor at Stanford University Medical School, a physician, epidemiologist, health economist, and public health policy expert focusing on infectious diseases and vulnerable populations.

SIGN THE DECLARATION

Co-signers

Medical and Public Health Scientists and Medical Practitioners

Dr. Alexander Walker, principal at World Health Information Science Consultants, former Chair of Epidemiology, Harvard TH Chan School of Public Health, USA

Dr. Andrius Kavaliunas, epidemiologist and assistant professor at Karolinska Institute, Sweden

Dr. Angus Dalgleish, oncologist, infectious disease expert and professor, St. George's Hospital Medical School, University of London, England

Dr. Anthony J Brookes, professor of genetics, University of Leicester, England

Dr. Annie Janvier, professor of pediatrics and clinical ethics, Université de Montréal and Sainte-Justine University Medical Centre, Canada

Dr. Ariel Munitz, professor of clinical microbiology and immunology, Tel Aviv University, Israel

Dr. Boris Kotchoubey, Institute for Medical Psychology, University of Tübingen, Germany

Dr. Cody Meissner, professor of pediatrics, expert on vaccine development, efficacy, and safety. Tufts University School of Medicine, USA

Dr. David Katz, physician and president, True Health Initiative, and founder of the Yale University Prevention Research Center, USA

Dr. David Livermore, microbiologist, infectious disease epidemiologist and professor, University of East Anglia, England

Dr. Eitan Friedman, professor of medicine, Tel-Aviv University, Israel

Dr. Ellen Townsend, professor of psychology, head of the Self-Harm Research Group, University of Nottingham, England

Dr. Eyal Shahar, physician, epidemiologist and professor (emeritus) of public health, University of Arizona, USA

Dr. Florian Limbourg, physician and hypertension researcher, professor at Hannover Medical School, Germany

Dr. Gabriela Gomes, mathematician studying infectious disease epidemiology, professor, University of Strathclyde, Scotland

Dr. Gerhard Krönke, physician and professor of translational immunology, University of Erlangen-Nuremberg, Germany

Dr. Helen Colhoun, professor of medical informatics and epidemiology, and public health physician, University of Edinburgh, Scotland

Dr. Laura Lazzeroni, professor of psychiatry and behavioral sciences and of biomedical data science, Stanford University Medical School, USA

Dr. Matthew Ratcliffe, professor of philosophy, specializing in philosophy of mental health, University of York, England

Dr. Michael Levitt, biophysicist and professor of structural biology, Stanford University, USA. Recipient of the 2013 Nobel Prize in Chemistry.

Dr. Partha P. Majumder, professor and founder of the National Institute of Biomedical Genomics, Kalyani, India

Dr. Gesine Weckmann, professor of health education and prevention, Europäische Fachhochschule, Rostock, Germany

Dr. Jonas Ludvigsson, pediatrician, epidemiologist and professor at Karolinska Institute and senior physician at Örebro University Hospital, Sweden

Dr. Lisa White, professor of modelling and epidemiology, Oxford University, England

Dr. Matthew Strauss, critical care physician and assistant professor of medicine, Queen's University, Canada

Dr. Mike Hulme, professor of human geography, University of Cambridge, England

Dr. Paul McKeigue, physician, disease modeler and professor of epidemiology and public health, University of Edinburgh, Scotland

Dr. Günter Kampf, associate professor, Institute for Hygiene and Environmental Medicine, Greifswald University, Germany

Dr. Karol Sikora, physician, oncologist, and professor of medicine at the University of Buckingham, England

Dr. Mario Recker, malaria researcher and associate professor, University of Exeter, England

Dr. Michael Jackson, research fellow, School of Biological Sciences, University of Canterbury, New Zealand

Dr. Motti Gerlic, professor of clinical microbiology and immunology, Tel Aviv University, Israel

Dr. Rajiv Bhatia, physician, epidemiologist and public policy expert at the Veterans Administration, USA

Dr. Rodney Sturdivant, infectious disease scientist and associate professor of biostatistics, Baylor University, USA

Dr. Simon Wood, biostatistician and professor, University of Edinburgh, Scotland

Tom Nicholson, Associate in Research, Duke Center for International Development, Sanford School of Public Policy, Duke University, USA

Dr. Uri Gavish, biomedical consultant, Israel

Dr. Salmaan Keshavjee, professor of Global Health and Social Medicine at Harvard Medical School, USA

Dr. Stephen Bremner,professor of medical statistics, University of Sussex, England

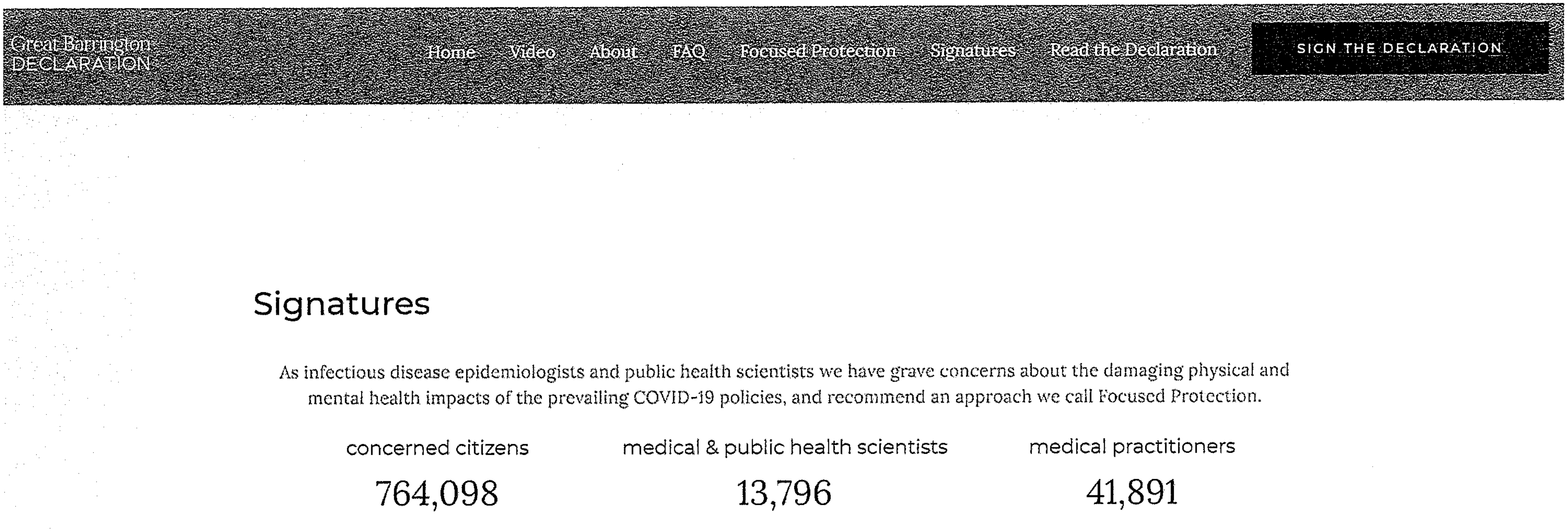
Dr. Udi Qimron, professor of clinical microbiology and immunology, Tel Aviv University, Israel

Dr. Yaz Gulnur Muradoglu, professor of finance, director of the Behavioural Finance Working Group, Queen Mary University of London, England

Dr. Simon Thornley, epidemiologist and biostatistician, University of Auckland, New Zealand

Dr. Sylvia Fogel, autism provider and psychiatrist at Massachusetts General Hospital and instructor at Harvard Medical School, USA

Dr. Ulrike Kämmerer, professor and expert in virology, immunology and cell biology, University of Würzburg, Germany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Signatures

As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

concerned citizens	medical & public health scientists	medical practitioners
764,098	13,796	41,891

https://gbdeclaration.org/view-signatures/

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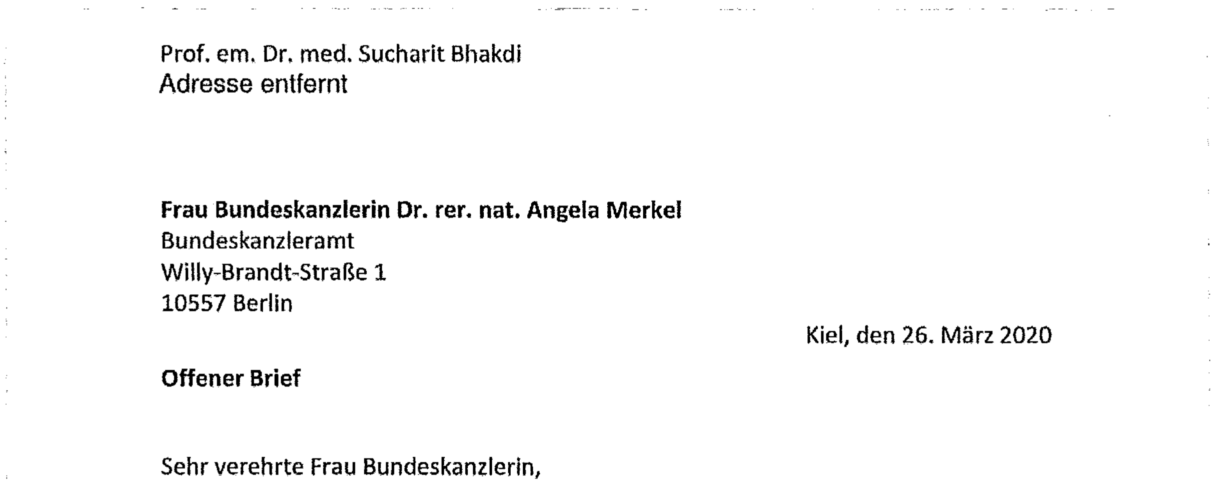
Open Letter from Professor Sucharit Bhakdi to German Chancellor Dr. Angela Merkel



Prof. em. Dr. med. Sucharit Bhakdi
Adresse entfernt

Frau Bundeskanzlerin Dr. rer. nat. Angela Merkel
Bundeskanzleramt
Willy-Brandt-Straße 1
10557 Berlin

Kiel, den 26. März 2020

Offener Brief

Sehr verehrte Frau Bundeskanzlerin,

Languages: DE, EN; EE, ES, FR, GR, HE, IT, NL, PT, RU, SK, TR
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An Open Letter from Dr. Sucharit Bhakdi, Professor Emeritus of Medical Microbiology at the Johannes Gutenberg University Mainz, to the German Chancellor Dr. Angela Merkel.

Professor Bhakdi calls for an urgent reassessment of the response to Covid-19 and asks the Chancellor five crucial questions. The letter is dated March 26. This is an inofficial translation; see the original letter in German as a PDF.

Open Letter

Dear Chancellor,

As Emeritus of the Johannes-Gutenberg-University in Mainz and longtime director of the Institute for Medical Microbiology, I feel obliged to critically question the far-reaching restrictions on public life that we are currently taking on ourselves in order to reduce the spread of the COVID-19 virus.

It is expressly not my intention to play down the dangers of the virus or to spread a political message. However, I feel it is my duty to make a scientific contribution to putting the current data and facts into perspective – and, in addition, to ask questions that are in danger of being lost in the heated debate.

The reason for my concern lies above all in the truly unforeseeable socio-economic consequences of the drastic containment measures which are currently being applied in large parts of Europe and which are also already being practiced on a large scale in Germany.

My wish is to discuss critically – and with the necessary foresight – the advantages and disadvantages of restricting public life and the resulting long-term effects.

To this end, I am confronted with five questions which have not been answered sufficiently so far, but which are indispensable for a balanced analysis.

I would like to ask you to comment quickly and, at the same time, appeal to the Federal Government to develop strategies that effectively protect risk groups without restricting public life across the board and sow the seeds for an even more intensive polarization of society than is already taking place.

With the utmost respect,

Prof. em. Dr. med. Sucharit Bhakdi

1. Statistics

In infectiology – founded by Robert Koch himself – a traditional distinction is made between infection and disease. An illness requires a clinical manifestation. [1] Therefore, only patients with symptoms such as fever or cough should be included in the statistics as new cases.

In other words, a new infection – as measured by the COVID-19 test – does not necessarily mean that we are dealing with a newly ill patient who needs a hospital bed. However, it is currently assumed that five percent of all infected people become seriously ill and require ventilation. Projections based on this estimate suggest that the healthcare system could be overburdened.

My question: Did the projections make a distinction between symptom-free infected people and actual, sick patients – i.e. people who develop symptoms?

2. Dangerousness

A number of coronaviruses have been circulating for a long time – largely unnoticed by the media. [2] If it should turn out that the COVID-19 virus should not be ascribed a significantly higher risk potential than the already circulating corona viruses, all countermeasures would obviously become unnecessary.

The internationally recognized *International Journal of Antimicrobial Agents* will soon publish a paper that addresses exactly this question. Preliminary results of the study can already be seen today and lead to the conclusion that the new virus is NOT different from traditional corona viruses in terms of dangerousness. The authors express this in the title of their paper "SARS-CoV-2: Fear versus Data". [3]

My question: How does the current workload of intensive care units with patients with diagnosed COVID-19 compare to other coronavirus infections, and to what extent will this data be taken into account in further decision-making by the federal government? In addition: Has the above study been taken into account in the planning so far? Here too, of course, "diagnosed" means that the virus plays a decisive role in the patient's state of illness, and not that previous illnesses play a greater role.

3. Dissemination

According to a report in the Süddeutsche Zeitung, not even the much-cited Robert Koch Institute knows exactly how much is tested for COVID-19. It is a fact, however, that a rapid increase in the number of cases has recently been observed in Germany as the volume of tests increases. [4]

It is therefore reasonable to suspect that the virus has already spread unnoticed in the healthy population. This would have two consequences: firstly, it would mean that the official death rate – on 26 March 2020, for example, there were 206 deaths from around 37,300 infections, or 0.55 percent [5] – is too high; and secondly, it would mean that it would hardly be possible to prevent the virus from spreading in the healthy population.

My question: Has there already been a random sample of the healthy general population to validate the real spread of the virus, or is this planned in the near future?

4. Mortality

The fear of a rise in the death rate in Germany (currently 0.55 percent) is currently the subject of particularly intense media attention. Many people are worried that it could shoot up like in Italy (10 percent) and Spain (7 percent) if action is not taken in time.

At the same time, the mistake is being made worldwide to report virus-related deaths as soon as it is established that the virus was present at the time of death – regardless of other factors. This violates a basic principle of infectiology: only when it is certain that an agent has played a significant role in the disease or death may a diagnosis be made. The *Association of the Scientific Medical Societies of Germany* expressly writes in its guidelines: "In addition to the cause of death, a causal chain must be stated, with the corresponding underlying disease in third place on the death certificate. Occasionally, four-linked causal chains must also be stated." [6]

At present there is no official information on whether, at least in retrospect, more critical analyses of medical records have been undertaken to determine how many deaths were actually caused by the virus.

My question: Has Germany simply followed this trend of a COVID-19 general suspicion? And: is it intended to continue this categorisation uncritically as in other countries? How, then, is a distinction to be made between genuine corona-related deaths and accidental virus presence at the time of death?

5. Comparability

The appalling situation in Italy is repeatedly used as a reference scenario. However, the true role of the virus in that country is completely unclear for many reasons – not only because points 3 and 4 above also apply here, but also because exceptional external factors exist which make these regions particularly vulnerable.

One of these factors is the increased air pollution in the north of Italy. According to WHO estimates, this situation, even without the virus, led to over 8,000 additional deaths per year in 2006 in the 13 largest cities in Italy alone. [7] The situation has not changed significantly since then. [8] Finally, it has also been shown that air pollution greatly increases the risk of viral lung diseases in very young and elderly people. [9]

Moreover, 27.4 percent of the particularly vulnerable population in this country live with young people, and in Spain as many as 33.5 percent. In Germany, the figure is only seven percent [10]. In addition, according to Prof. Dr. Reinhard Busse, head of the Department

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of Management in Health Care at the TU Berlin, Germany is significantly better equipped than Italy in terms of intensive care units – by a factor of about 2.5 [11].

My question: What efforts are being made to make the population aware of these elementary differences and to make people understand that scenarios like those in Italy or Spain are not realistic here?

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CARTA ABIERTA

Nosotros, médicos y profesionales de la salud belgas, deseamos expresar nuestra seria preocupación por la evolución de la situación en los últimos meses en torno al brote del virus SARS-CoV-2. Hacemos un llamado a los políticos para que estén informados de manera independiente y crítica en el proceso de toma de decisiones y en la implementación obligatoria de las medidas corona. Solicitamos un debate abierto, donde todos los expertos estén representados sin ningún tipo de censura. Después del pánico inicial que rodeó al covid-19, los hechos objetivos ahora muestran una imagen completamente diferente: ya no hay justificación médica para ninguna política de emergencia.

La gestión actual de la crisis se ha vuelto totalmente desproporcionada y causa más daño que bien.

Pedimos el fin de todas las medidas y pedimos una restauración inmediata de nuestra gobernanza democrática y estructuras legales normales y de todas nuestras libertades civiles.

"Una cura no debe ser peor que el problema" es una tesis que es más relevante que nunca en la situación actual. Sin embargo, observamos que el daño colateral que ahora se está causando a la población tendrá un impacto mayor a corto y largo plazo en todos los sectores de la población que el número de personas que ahora están protegidas del coronavirus

En nuestra opinión, las actuales medidas y las estrictas sanciones por su incumplimiento son contrarias a los valores formulados por el Consejo Supremo de Salud de Bélgica, que, hasta hace poco, como autoridad sanitaria, siempre ha asegurado una medicina de calidad en nuestro país: "Ciencia - Experiencia - Calidad - Imparcialidad - Independencia - Transparencia". 1

Creemos que la política ha introducido medidas obligatorias que no están suficientemente fundamentadas científicamente, dirigidas unilateralmente, y que no hay suficiente espacio en los medios de comunicación para un debate abierto en el que se escuchen diferentes puntos de vista y opiniones. Además, cada municipio y provincia tiene ahora la autorización para agregar sus propias medidas, bien fundamentadas o no.

Además, la estricta política represiva sobre coronavirus, contrasta fuertemente con la política mínima del gobierno en lo que respecta a la prevención de enfermedades, el fortalecimiento de nuestro propio sistema inmunológico a través de un estilo de vida saludable, una atención óptima con atención al individuo y la inversión en el personal de atención. 2

El concepto de salud

En 1948, la OMS definió la salud de la siguiente manera: "La salud es un estado de completo bienestar físico, mental y social y no simplemente la ausencia de enfermedad u otro impedimento físico" 3

La salud, por tanto, es un concepto amplio que va más allá de lo físico y también se relaciona con el bienestar emocional y social del individuo. Bélgica también tiene el deber, desde el punto de vista de la suscripción de los derechos humanos fundamentales, de incluir estos derechos humanos en su toma de decisiones cuando se trata de medidas adoptadas en el contexto de la salud pública. 4

Las actuales medidas globales adoptadas para combatir el SARS-CoV-2 violan en gran medida esta visión de la salud y los derechos humanos. Las medidas incluyen el uso obligatorio de máscarilla (también al aire libre y durante las actividades deportivas, y en algunos municipios incluso cuando no hay otras personas en las proximidades), el distanciamiento físico, el aislamiento social, la cuarentena obligatoria para algunos grupos y las medidas de higiene.

La pandemia predicha con millones de muertes

Al comienzo de la pandemia, las medidas eran comprensibles y contaban con un amplio apoyo, incluso si había diferencias en la implementación en los países que nos rodean. La OMS predijo originalmente una pandemia que cobraría un 3,4% de víctimas, es decir millones de muertes, y un virus altamente contagioso para el que no se disponía de tratamiento ni vacuna. Esto pondría una presión sin precedentes sobre las unidades de cuidados intensivos (UCI) de nuestros hospitales.

Esto condujo a una situación de alarma global, nunca vista en la historia de la humanidad: “aplanar la curva” estuvo representado por un bloqueo que cerró a toda la sociedad y la economía y puso en cuarentena a las personas sanas. El distanciamiento social se convirtió en la nueva normalidad en previsión de una vacuna de rescate.

Los hechos sobre covid-19

Gradualmente, la campana de alarma fue sonando desde muchas fuentes: los hechos objetivos mostraban una realidad completamente diferente.

El curso de covid-19 siguió el curso de una ola normal de infección similar a una temporada de gripe. Como cada año, vemos una mezcla de virus de influenza siguiendo la curva: primero los rinovirus, luego los virus de influenza A y B, seguidos de los coronavirus. No hay nada diferente a lo que vemos normalmente.

El uso de la prueba de PCR inespecífica, que produce muchos falsos positivos, mostró un panorama exponencial. Esta prueba se apresuró a realizar con un procedimiento de emergencia y nunca se autocomprobó seriamente. El creador advirtió expresamente que esta prueba estaba destinada a la investigación y no al diagnóstico.

La prueba de PCR funciona con ciclos de amplificación de material genético: cada vez se amplifica una parte del genoma. Cualquier contaminación (por ejemplo, otros virus, restos de genomas de virus antiguos) puede dar lugar a falsos positivos.

La prueba no mide cuántos virus hay en la muestra. Una infección viral real significa una presencia masiva de virus, la llamada carga de virus. Si alguien da positivo, esto no significa que esa persona en realidad esté clínicamente infectada, esté enferma o vaya a enfermarse. El postulado de Koch no se cumplió ("El agente puro que se encuentra en un paciente con quejas puede provocar las mismas quejas en una persona sana").

Dado que una prueba de PCR positiva no indica automáticamente una infección activa o infectividad, esto no justifica las medidas sociales tomadas, que se basan únicamente en estas pruebas.

Cierre de emergencia

Si comparamos las oleadas de infección en países con políticas de bloqueo estrictas con países que no impusieron bloqueos (Suecia, Islandia...), vemos curvas similares. Por tanto, no existe ningún vínculo entre el bloqueo impuesto y el curso de la infección. El bloqueo no ha dado lugar a una tasa de mortalidad más baja.

Si miramos la fecha de aplicación de los bloqueos impuestos, vemos que los bloqueos se establecieron después de que el pico ya había pasado y el número de casos disminuyó. Por tanto, la caída no fue el resultado de las medidas adoptadas. 11

Como cada año, parece que las condiciones climáticas (clima, temperatura y humedad) y la creciente inmunidad tienen más probabilidades de reducir la ola de infección.

Nuestro sistema inmunológico

Durante miles de años, el cuerpo humano ha estado expuesto diariamente a la humedad y a las gotitas que contienen microorganismos infecciosos (virus, bacterias y hongos).

La penetración de estos microorganismos se evita mediante un mecanismo de defensa avanzado: el sistema inmunológico. Un sistema inmunológico fuerte depende de la exposición diaria normal a estas influencias microbianas. Las medidas excesivamente higiénicas tienen un efecto perjudicial sobre nuestra inmunidad. 12 13 Solo las personas con un sistema inmunológico débil o defectuoso deben estar protegidas mediante una higiene intensiva o un distanciamiento social.

La influenza reaparecerá en otoño (en combinación con el covid-19) y una posible disminución de la resiliencia natural puede provocar más víctimas.

Nuestro sistema inmunológico consta de dos partes: un sistema inmunológico congénito no específico y un sistema inmunológico adaptativo.

El sistema inmunológico inespecífico forma una primera barrera: piel, saliva, jugo gástrico, moco intestinal, células ciliadas vibratorias, flora comensal,... y evita la adhesión de microorganismos a los tejidos.

Si se adhieren, los macrófagos pueden hacer que los microorganismos se encapsulen y destruyan.

El sistema inmunológico adaptativo está formado por inmunidad de las mucosas (anticuerpos IgA, producidos principalmente por las células del intestino y el epitelio pulmonar), inmunidad celular (activación de células T), que puede generarse en contacto con sustancias extrañas o microorganismos, e inmunidad humoral (IgM y anticuerpos IgG producidos por las células B).

Investigaciones recientes muestran que ambos sistemas están muy enredados.

Parece que la mayoría de las personas ya tienen inmunidad congénita o general a p. Ej. influenza y otros virus. Esto es confirmado por los hallazgos en el crucero Diamond Princess, que fue puesto en cuarentena debido a que algunos pasajeros murieron de Covid-19. La mayoría de los pasajeros eran ancianos y se encontraban en una situación ideal de transmisión en el barco. Sin embargo, el 75% no parecía estar infectado. Entonces, incluso en este grupo de alto riesgo, la mayoría son resistentes al virus.

Un estudio de la revista Cell muestra que la mayoría de las personas neutralizan el coronavirus mediante la inmunidad mucosa (IgA) y celular (células T), mientras experimentan pocos o ningún síntoma 14.

Los investigadores encontraron hasta un 60% de reactividad del SARS-Cov-2 con las células T CD4 + en una población no infectada, lo que sugiere una reactividad cruzada con otros virus del resfriado (coronavirus) .15

Por lo tanto, la mayoría de las personas ya tienen una inmunidad congénita o cruzada porque ya estaban en contacto con variantes del mismo virus.

La formación de anticuerpos (IgM e IgG) por las células B solo ocupa una parte relativamente pequeña de nuestro sistema inmunológico. Esto puede explicar por qué, con un porcentaje de anticuerpos del 5 al 10%, puede haber una inmunidad de grupo de todos modos. La eficacia de las vacunas se evalúa precisamente en función de si tenemos o no estos anticuerpos. Esta es una tergiversación.

La mayoría de las personas que dan positivo en la prueba (PCR) no tienen quejas. Su sistema inmunológico es lo suficientemente fuerte. Fortalecer la inmunidad natural es un enfoque mucho más lógico. La prevención es un pilar importante, insuficientemente destacado: nutrición sana y completa, ejercicio al aire libre, sin mascarilla, reducción del estrés y contactos emocionales y sociales nutritivos.

Consecuencias del aislamiento social en la salud física y mental

El aislamiento social y el daño económico llevaron a un aumento de la depresión, la ansiedad, los suicidios, la violencia intrafamiliar y el abuso infantil16.

Los estudios han demostrado que cuanto más compromisos sociales y emocionales tienen las personas, más resistentes son a los virus. Es mucho más probable que el aislamiento y la cuarentena tengan consecuencias fatales. 17

Las medidas de aislamiento también han llevado a la inactividad física de muchas personas mayores debido a que se han visto obligadas a permanecer en el interior. Sin embargo, el ejercicio suficiente tiene un efecto positivo en el funcionamiento cognitivo, reduciendo los síntomas depresivos y la ansiedad y mejorando la salud física, los niveles de energía, el bienestar y, en general, la calidad de vida18.

El miedo, el estrés persistente y la soledad inducidos por el distanciamiento social tienen una influencia negativa demostrada en la salud psicológica y general. 19

¿Un virus altamente contagioso con millones de muertes sin ningún tratamiento?

La mortalidad resultó ser muchas veces menor de lo esperado y cercana a la de una gripe estacional normal (0,2%). 20

Por lo tanto, el número de muertes por Covid-19 registradas todavía parece estar sobreestimado.

Existe una diferencia entre la muerte por Covid-19 y la muerte por otros Coronavirus. Los seres humanos a menudo son portadores de múltiples virus y bacterias potencialmente patógenas al mismo tiempo. Teniendo en cuenta el hecho de que la mayoría de las personas que desarrollaron síntomas graves padecían patologías adicionales, no se puede simplemente concluir que la infección por SARS-CoV-2 fué la causa de la muerte. En la mayoría de los casos, esto no se tuvo en cuenta en las estadísticas.

Los grupos más vulnerables pueden identificarse claramente. La gran mayoría de los pacientes fallecidos tenían 80 años o más. La mayoría (70%) de los fallecidos, menores de 70 años, tenían algún trastorno subyacente, como sufrimiento cardiovascular, diabetes mellitus, enfermedad pulmonar crónica u obesidad. La gran mayoría de las personas infectadas (> 98%) no se enfermaron o apenas se enfermaron o se recuperaron espontáneamente.

Mientras tanto, existe una terapia asequible, segura y eficiente disponible para aquellos que muestran síntomas graves de enfermedad en forma de HCQ (hidroxicloroquina), zinc y AZT (azitromicina). Esta terapia aplicada rápidamente conduce a la recuperación y, a menudo, evita la hospitalización. Casi nadie tiene que morir ahora.

Esta terapia eficaz ha sido confirmada por la experiencia clínica de colegas en el campo con resultados impresionantes. Esto contrasta marcadamente con la crítica teórica (fundamentación insuficiente de los estudios doble ciego) que en algunos países (por ejemplo, los Países Bajos) incluso ha llevado a la prohibición de esta terapia. Se retiró un metanálisis en The Lancet, que no pudo demostrar un efecto de HCQ. Las fuentes de datos primarias utilizadas demostraron ser poco fiables y 2 de cada 3 autores estaban en conflicto de intereses. Sin embargo, la mayoría de las pautas basadas en este estudio se mantuvieron sin cambios ... 48 49

Tenemos serias dudas sobre este estado de cosas.

En los EE. UU., Un grupo de médicos en el campo, que atienden a pacientes a diario, se unieron en "America's Frontline Doctors" y dieron una conferencia de prensa que ha sido vista millones de veces.21 51

El profesor francés Didier Raoult del Institut d'Infectiologie de Marseille (IHU) también presentó esta terapia combinada prometedora ya en abril. El médico de cabecera holandés Rob Elens, que curó a muchos pacientes en su consulta con HCQ y zinc, llamó a sus colegas en una petición para la libertad de terapia.22

La evidencia definitiva proviene del seguimiento epidemiológico en Suiza: tasas de mortalidad comparadas con y sin esta terapia23.

A partir de las angustiosas imágenes de los medios de comunicación del SDRA (síndrome de dificultad respiratoria aguda) en las que las personas se asfixiaban y recibían respiración artificial en agonía, ahora sabemos que esto fue causado por una respuesta inmune exagerada con coagulación intravascular en los vasos sanguíneos pulmonares. La administración de anticoagulantes y dexametasona y la evitación de la ventilación artificial, que se encontró que causa daño adicional al tejido pulmonar, significa que esta temida complicación tampoco es virtualmente fatal. 47

Por lo tanto, no es un virus asesino, sino una afección que se puede tratar bien.

Propagación

La propagación se produce por infecciones por goteo (solo para pacientes que tosen o estornudan) y aerosoles en habitaciones cerradas y sin ventilación. Por tanto, la contaminación no es posible al aire libre. Los estudios epidemiológicos y de rastreo de contactos muestran que las personas sanas (o portadores asintomáticos sometidos a pruebas positivas) son prácticamente incapaces de transmitir el virus. Las personas sanas, por tanto, no se ponen en riesgo unas a otras. 24 25

La transferencia a través de objetos (por ejemplo, dinero, compras o carritos de compra) no ha sido científicamente probada26 27 28.

Todo esto cuestiona seriamente toda la política de distanciamiento social y mascarillas obligatorias para las personas sanas; no hay base científica para ello.

Mascarillas

Las mascarillas pertenecen a contextos en los que tienen lugar contactos con grupos de riesgo comprobados o personas con problemas de las vías respiratorias superiores, y en un contexto médico / entorno hospitalario-asilo de ancianos. Reducen el riesgo de infección por gotitas al estornudar o toser. Las mascarillas en individuos sanos son ineficaces contra la propagación de infecciones virales. 29 30 31

El uso de una mascarilla no está exento de efectos secundarios. 32 33 La deficiencia de oxígeno (dolor de cabeza, náuseas, fatiga, pérdida de concentración) ocurre con bastante rapidez, un efecto similar al mal de altura. Todos los días vemos a pacientes que se quejan de dolores de cabeza, problemas de los senos nasales, problemas respiratorios e hiperventilación debido al uso de máscaras. Además, el CO2 acumulado provoca una acidificación tóxica del organismo que afecta nuestra inmunidad. Algunos expertos incluso advierten de un aumento de la transmisión del virus en caso de uso inadecuado de la máscara34.

Nuestro Código Laboral (Codex 6) se refiere a un contenido de CO2 (ventilación en los lugares de trabajo) de 900 ppm, máximo 1200 ppm en circunstancias especiales. Después de usar una mascarilla durante un minuto, este límite tóxico se supera considerablemente a valores que son de tres a cuatro veces superiores a estos valores máximos. Cualquiera que use una mascarilla se encuentra, por lo tanto, en una habitación extremadamente mal ventilada. 35

Por lo tanto, especialistas reconocidos en seguridad no recomiendan a los trabajadores el uso inadecuado de mascarilla sin un archivo completo de pruebas cardiopulmonares médicas.

Los hospitales tienen un ambiente estéril en sus quirófanos donde el personal usa mascarilla y existe una regulación precisa de la humedad / temperatura con un flujo de oxígeno adecuadamente monitoreado para compensar esto, cumpliendo así con estrictos estándares de seguridad. 36

¿Una segunda ola de coronavirus?

Ahora se está discutiendo una segunda ola en Bélgica, con un mayor endurecimiento de las medidas como resultado. Sin embargo, un examen más detenido de las cifras de Sciensano (último informe del 3 de septiembre de 2020) 37 muestra que, aunque ha habido un aumento en el número de infecciones desde mediados de julio, no hubo un aumento en las admisiones hospitalarias o muertes en ese momento. Por lo tanto, no se trata de una segunda ola de coronavirus, sino de la denominada "química del caso" debido a un mayor número de pruebas. 50

El número de ingresos hospitalarios o fallecidos mostró un aumento mínimo de corta duración en las últimas semanas, pero al interpretarlo hay que tener en cuenta la reciente ola de calor. Además, la gran mayoría de las víctimas aún se encuentran en el grupo de población> 75 años.

Esto indica que la proporción de las medidas tomadas en relación con la población activa y los jóvenes es desproporcionada con los objetivos previstos.

La gran mayoría de las personas "infectadas" con pruebas positivas se encuentran en el grupo de edad de la población activa, que no desarrolla ningún síntoma o simplemente presenta síntomas limitados, debido al buen funcionamiento del sistema inmunológico.

Así que nada ha cambiado, se acabó el pico.

Fortalecimiento de una política de prevención

Las medidas del coronavirus contrastan notablemente con la política mínima seguida por el gobierno hasta ahora, cuando se trata de medidas bien fundamentadas con beneficios para la salud comprobados como el impuesto al azúcar, la prohibición de los cigarrillos (electrónicos) y la elaboración de alimentos saludables, ejercicio. y redes de apoyo social económicamente atractivas y ampliamente accesibles. Es una oportunidad perdida para una mejor política de prevención que podría haber provocado un cambio de mentalidad en todos los sectores de la población con resultados claros en términos de salud pública. En la actualidad, solo el 3% del presupuesto sanitario se destina a la prevención. 2

El juramento hipocrático

Como médico, hicimos el juramento hipocrático:

"Sobre todo cuidaré de mis pacientes, promoveré su salud y aliviaré su sufrimiento".

"Informaré a mis pacientes correctamente".

"Incluso bajo presión, no utilizaré mis conocimientos médicos para prácticas que sean contra la humanidad".

Las medidas actuales nos obligan a actuar contra este juramento.

Otros profesionales de la salud tienen un código similar.

El "primum non nocere", que todo médico y profesional de la salud asume, también se ve socavado por las medidas actuales y por la perspectiva de la posible introducción de una vacuna generalizada, que no está sujeta a extensas pruebas previas.

Vacuna

Los estudios de encuestas sobre vacunas contra la influenza muestran que en 10 años solo hemos logrado tres veces desarrollar una vacuna con una tasa de eficiencia de más del 50%. Vacunar a nuestros ancianos parece ineficaz. Más de 75 años, la eficacia es casi nula38.

Debido a la continua mutación natural de los virus, como también vemos todos los años en el caso del virus de la influenza, una vacuna es como mucho una solución temporal, que requiere nuevas vacunas cada vez después. Una vacuna no probada, que se implementa mediante un procedimiento de emergencia y para la cual los fabricantes ya han obtenido inmunidad legal ante posibles daños, plantea serias preguntas. 39 40 No deseamos utilizar a nuestros pacientes como conejillos de indias.

A escala mundial, se esperan 700000 casos de daños o muerte como resultado de la vacuna.41

Si el 95% de las personas experimentan Covid-19 prácticamente sin síntomas, el riesgo de exposición a una vacuna no probada es irresponsable.

El papel de los medios de comunicación y el plan oficial de comunicación

Durante los últimos meses, los fabricantes de periódicos, radio y televisión parecían estar casi acríticamente detrás del panel de expertos y del gobierno, allí, donde es precisamente la prensa la que debe ser crítica y evitar la comunicación gubernamental unilateral. Esto ha llevado a una comunicación pública en nuestros medios de comunicación, que era más una propaganda que un informe objetivo.

En nuestra opinión, es tarea del periodismo llevar las noticias de la manera más objetiva y neutral posible, con el objetivo de encontrar la verdad y controlar críticamente el poder, y los expertos disidentes también tienen un foro en el que expresarse.

Esta visión está respaldada por los códigos deontológicos periodísticos42.

La historia oficial de que un bloqueo era necesario, que esta era la única solución posible y que todos estaban detrás de este bloqueo, hizo que fuera difícil para las personas con una opinión diferente, así como para los expertos, expresar una opinión diferente.

Las opiniones alternativas fueron ignoradas o ridiculizadas. No hemos visto debates abiertos en los medios de comunicación, donde se puedan expresar diferentes puntos de vista.

También nos sorprendieron los numerosos videos y artículos de muchos expertos científicos y autoridades, que fueron y aún están siendo eliminados de las redes sociales. Creemos que esto no encaja con un Estado constitucional democrático y libre, tanto más cuanto conduce a una visión de túnel. Esta política también tiene un efecto paralizante y alimenta el miedo y la preocupación en la sociedad. En este contexto, ¡rechazamos la intención de censurar a los disidentes en la Unión Europea! 43

La forma en que los políticos y los medios de comunicación han retratado a Covid-19 tampoco le ha hecho ningún bien a la situación. Los términos de guerra eran populares y no faltaba el lenguaje bélico. A menudo se ha mencionado una "guerra" con un "enemigo invisible" que debe ser "derrotado". El uso en los medios de comunicación de frases como "héroes del cuidado en primera línea" y "víctimas de coronavirus " ha alimentado aún más el miedo, al igual que la idea de que estamos lidiando globalmente con un "virus asesino".

El implacable bombardeo con cifras, que se desató sobre la población día tras día, hora tras hora, sin interpretar esas cifras, sin compararlas con las muertes por gripe en otros años, sin compararlas con las muertes por otras causas, ha inducido una verdadera psicosis de miedo en la población. Esto no es información, es manipulación.

Deploramos el papel de la OMS en esto, que ha pedido que la infodemia (es decir, todas las opiniones divergentes del discurso oficial, incluidas las de expertos con diferentes puntos de vista) sea silenciada por una censura de medios sin precedentes43. 44

¡Hacemos un llamado urgente a los medios de comunicación para que asuman sus responsabilidades aquí!

Exigimos un debate abierto en el que se escuche a todos los expertos.

Ley de emergencia versus derechos humanos

El principio general de buena gobernanza exige que la proporcionalidad de las decisiones gubernamentales se sopese a la luz de los estándares legales más altos: cualquier interferencia del gobierno debe respetar los derechos fundamentales protegidos en el Convenio Europeo de Derechos Humanos (CEDH). La interferencia de las autoridades públicas solo está permitida en situaciones de crisis. En otras palabras, las decisiones discrecionales deben ser proporcionadas a una necesidad absoluta.

Las medidas actualmente adoptadas se refieren a la injerencia en el ejercicio, entre otras cosas, del derecho al respeto de la vida privada y familiar, la libertad de pensamiento, conciencia y religión, la libertad de expresión y la libertad de reunión y asociación, el derecho a la educación, etc. , y por lo tanto debe respetar los derechos fundamentales protegidos por el Convenio Europeo de Derechos Humanos (CEDH).

Por ejemplo, de conformidad con el artículo 8 (2) del CEDH, la injerencia en el derecho a la vida privada y familiar solo está permitida si las medidas son necesarias en interés de la seguridad nacional, la seguridad pública y el bienestar económico del país. , la protección del orden público y la prevención de delitos, la protección de la salud o la protección de los derechos y libertades de los demás, el texto normativo en el que se basa la injerencia debe ser suficientemente claro, previsible y proporcionado a los objetivos perseguidos. 45

La pandemia predicha de millones de muertes pareció responder a estas condiciones de crisis, lo que llevó al establecimiento de un gobierno de emergencia. Ahora que los hechos objetivos muestran algo completamente diferente, la condición de incapacidad para actuar de otra manera (no hay tiempo para evaluar a fondo si hay una emergencia) ya no existe. El Covid-19 no es un virus del resfriado, sino una afección bien tratable con una tasa de mortalidad comparable a la de la gripe estacional. En otras palabras, ya no existe un obstáculo insuperable para la salud pública.

No hay estado de emergencia.

Inmenso daño causado por las políticas actuales

Una discusión abierta sobre las medidas de coronavirus significa que, además de los años de vida ganados por los pacientes de coronavirus, también debemos tener en cuenta otros factores que afectan la salud de toda la población. Estos incluyen daños en el dominio psicosocial (aumento de la depresión, ansiedad, suicidios, violencia intrafamiliar y maltrato infantil) 16 y daños económicos.

Si tenemos en cuenta este daño colateral, la política actual es desproporcionada, el proverbial uso de un mazo para romper una nuez.

Nos sorprende que el gobierno invoque la salud como motivo de la ley de emergencia.

Como médicos y profesionales de la salud, ante un virus que, por su nocividad, mortalidad y transmisibilidad, se acerca a la influenza estacional, solo podemos rechazar estas medidas extremadamente desproporcionadas.

Por tanto, exigimos el fin inmediato de todas las medidas.

Estamos cuestionando la legitimidad de los expertos asesores actuales, que se reúnen a puerta cerrada.

Siguiendo con ACU 2020 46 https://acu2020.org/nederlandse-versie/, pedimos un examen en profundidad del papel de la OMS y la posible influencia de los conflictos de intereses en esta organización. También estuvo en el centro de la lucha contra la "infodemia", es decir, la censura sistemática de todas las opiniones disidentes en los medios de comunicación. Esto es inaceptable para un estado democrático gobernado por el estado de derecho.43

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No hay un resurgimiento de la pandemia, sino un supuesto casodemia debido a más pruebas.

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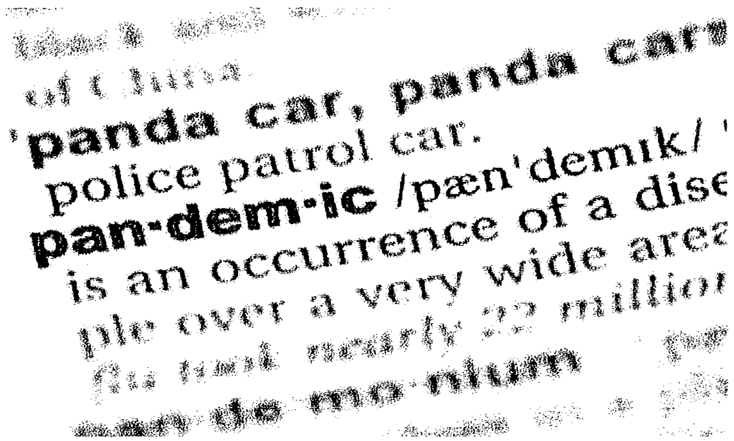
Las definiciones de pandemias, vacunas e inmunidad colectiva fueron modificadas

Análisis escrito por Dr. Joseph Mercola



'panda car, panda car

police patrol car.

pan·dem·ic /pæn'demɪk/

is an occurrence of a dise

ple over a very wide area

HISTORIA EN BREVE

- En los últimos años y meses, las definiciones antiguas de tres palabras cambiaron, y ahora tienen inmensas ramificaciones para la política de salud pública en medio del COVID-19
- La definición original de pandemia de la OMS del 1 de mayo de 2009 especificaba epidemias simultáneas en todo el mundo "con una gran cantidad de muertes y enfermedades"; esta definición cambió el mes previo a la pandemia de gripe porcina de 2009 y eliminó los criterios de gravedad y alta mortalidad
- Las vacunas del COVID-19 son técnicamente terapias génicas y no cumplían con la definición de vacuna, hasta que la definición de vacuna de Merriam-Webster cambió para incluir una descripción de las terapias génicas experimentales
- De junio a noviembre de 2020, la OMS cambió su definición de inmunidad colectiva para dar a entender que es un concepto que solo se aplica a la vacuna, no a la inmunidad que se adquiere de forma natural por una infección previa
- La consecuencia para la sociedad es que, al publicar esta información falsa, intentan cambiar su percepción de lo que es y lo que no es cierto, y corrompen la ciencia en el proceso

En el último año, ¿alguna vez ha sentido que vive en un sentido alterado de la realidad, donde las cosas que una vez supo que eran ciertas ya no lo son? No está en su imaginación. En los últimos años y meses, las definiciones antiguas de tres palabras cambiaron, y ahora tienen inmensas ramificaciones para la política de salud pública en medio del COVID-19.

La consecuencia aún mayor para la sociedad es que al publicar esta información falsa, intentan cambiar su percepción de lo que es cierto y lo que no es cierto, y corrompen la ciencia en el proceso.

La OMS cambió la definición de pandemia

¿Qué es exactamente una pandemia? La definición original de la OMS de una pandemia desde el 1 de mayo de 2009, especificó que eran epidemias simultáneas en todo el mundo "con una gran cantidad de muertes y enfermedades":

"Una pandemia de influenza ocurre cuando aparece un nuevo virus de influenza contra el cual la población humana no tiene inmunidad, lo que da como resultado varias epidemias simultáneas en todo el mundo con una gran cantidad de muertes y enfermedades".

Esta definición se cambió un mes antes de la pandemia de gripe porcina de 2009 al eliminar los criterios de gravedad y alta mortalidad y dejar la definición de pandemia como "una epidemia mundial de una enfermedad".

Este cambio de definición le permitió a la OMS declarar la gripe porcina como una pandemia después de que solo 144 personas murieran a causa de la infección en todo el mundo, y es por eso que el COVID-19 todavía se promueve como una pandemia a pesar de que muchos datos sugieren que la **letalidad del COVID-19** es igual a la de la gripe estacional.

Definición de vacuna modificada

Al referirse a las vacunas del COVID-19 como "vacunas" en lugar de terapias génicas, se viola el código 15 de la Sección 41 del gobierno de Estados Unidos. De acuerdo con esta ley, es ilegal divulgar:

"Que un producto o servicio puede prevenir, tratar o curar enfermedades humanas a menos que usted posea evidencia científica competente y confiable, incluyendo, cuando sea apropiado, estudios clínicos en humanos bien controlados, que demuestren que las afirmaciones son verdaderas en el momento en que se realizan".

Además, no puede tener una "vacuna" que no cumpla con la definición de vacuna. Hasta hace poco tiempo, Merriam-Webster definía vacuna como "una preparación de microorganismos muertos, organismos vivos atenuados u organismos vivos totalmente virulentos que se administra para producir o incrementar de forma artificial la inmunidad a una enfermedad en particular".

Las vacunas del COVID-19 no son vacunas convencionales elaboradas con virus vivos o atenuados. En realidad, son terapias génicas. Las vacunas de Pfizer y Moderna están elaboradas con nanopartículas lipídicas que contienen polietilenglicol (PEG) y ARN mensajero (ARNm).

Los ARNm son fragmentos de código genético que llevan instrucciones para que las células produzcan proteínas. La definición de genética se "relaciona con los genes" y los genes contienen un código de instrucción que le dice al cuerpo qué proteínas producir. La terapia es el tratamiento médico de la enfermedad, por lo que las vacunas de ARNm son una terapia génica.

Como señaló David Martin, Ph.D., las presentaciones ante la SEC de Moderna especifican y enfatizan que la FDA considera que su tecnología "de terapia génica", originalmente estaba destinada para tratar el cáncer. Su mecanismo de acción también lo confirma como terapia génica. Las terapias génicas de ARNm que se comercializan de forma engañosa como "vacunas" convierten sus células en biorreactores que producen proteínas virales para causar una respuesta inmunológica y no hay forma de detenerlo.

Dado que las "vacunas" del COVID-19 no cumplían con la definición anterior de vacuna, la definición de vacuna de Merriam-Webster cambió para incluir una descripción de las terapias génicas experimentales del COVID-19:

"Una preparación que se administra (por inyección) para estimular la respuesta inmunológica del cuerpo contra una enfermedad infecciosa específica:

a:una preparación antigénica de un agente patógeno típicamente inactivado, atenuado (ver sentido atenuado 2) (como una bacteria o virus) o uno de sus componentes o productos (como una proteína o toxina) *b:una preparación de material genético (como una hebra de ARN mensajero sintetizado) que utiliza las células del cuerpo para producir una sustancia antigénica (como un fragmento de la proteína Spike del virus)"*

Por qué no quieren que las vacunas del COVID se llamen terapia génica

Presentaciones de la SEC de Moderna, que, en el video anterior Martin afirma que revisó, especificó y enfatizó que su tecnología es una "tecnología de terapia génica". En un principio su tecnología se creó para ser un tratamiento contra el cáncer, por lo que, en realidad es una tecnología de terapia génica de quimioterapia.

Como señaló Martin, ¿quién levantaría la mano para recibir terapia génica de quimioterapia profiláctica para un cáncer que no tiene y que tal vez nunca tenga riesgo de padecer? Es muy probable que pocas personas aceptarían tal oferta y solo por una buena razón.

Los estados y los empleadores no podrían obligar a las personas a recibir terapia génica de quimioterapia para un cáncer que no tienen, ya que sería ilegal.

Sin embargo, proponen que toda la humanidad reciba la terapia génica del COVID-19 de forma obligatoria, Si realmente lo llamaran como es, "terapia génica dequiemioterapia", la mayoría de las personas se negarían a recibirla. Quizás esa sea una de las razones de su falsa categorización como vacunas.

Pero también podría haber otras razones. Martin no entra en conjeturas, ya que no tenemos pruebas de sus intenciones, pero especula que la razón por la que llaman a esta tecnología de terapia génica experimental una "vacuna" es porque al hacerlo, pueden eludir la responsabilidad por daños.

Mientras los Estados Unidos se encuentren en estado de emergencia, se permiten cosas como las pruebas de PCR y las "vacunas" del COVID-19 bajo autorización de uso de emergencia. Y, mientras la autorización de uso de emergencia esté en vigor, los fabricantes de estas terapias génicas experimentales no son responsables económicamente de ningún daño que se derive de su uso.

Es decir, siempre que sean "vacunas". Si estas inyecciones NO son vacunas, entonces el escudo de responsabilidad desaparece, porque no existe un escudo de responsabilidad para una contramedida de emergencia médica que es la terapia génica.

La OMS cambió la definición de inmunidad colectiva

En junio de 2020, la definición de inmunidad colectiva de la OMS, publicada en una de sus páginas de preguntas y respuestas sobre el COVID-19, estaba en línea con el concepto que ha sido el estándar para las enfermedades infecciosas durante décadas. Esto es lo que decía en un principio, cortesía del Internet Archive's Wayback machine:

"La inmunidad colectiva es la protección indirecta contra una enfermedad infecciosa que ocurre cuando una población es inmune, ya sea por una vacuna o por la inmunidad desarrollada a través de una infección previa".

Cabe señalar que "la inmunidad que se desarrolla por medio de una infección previa" es la forma en que ha funcionado desde que los humanos están vivos. Su **sistema inmunológico no está diseñado para recibir vacunas**. Está diseñado para funcionar en respuesta a la exposición a un agente infeccioso. Aparentemente, de acuerdo con la OMS, ese ya no es el caso. En octubre de 2020, aquí está su **definición actualizada de inmunidad colectiva**, que ahora es "un concepto que se utiliza para la vacuna":

"La 'inmunidad colectiva', también conocida como 'inmunidad de la población', es un concepto que se utiliza para la vacuna, en el que una población puede protegerse de un determinado virus si se alcanza un límite de vacunas. La inmunidad colectiva se logra al proteger a las personas de un virus, no al exponerlas a él.

Las vacunas entrenan a nuestro sistema inmunológico para crear proteínas que combaten las enfermedades, conocidas como "anticuerpos", tal como sucedería cuando nos exponemos a una enfermedad, pero, lo que es más importante, las vacunas funcionan sin enfermarnos. Las personas vacunadas están protegidas de contraer la enfermedad en cuestión y transmitirla, para romper cualquier cadena de transmisión".

En Twitter, la analista de investigación Heather Taylor publicó una captura de pantalla con las dos definiciones, una del 9 de junio de 2020 y la otra del 13 de noviembre de 2020, donde cambió para implicar que la inmunidad colectiva, en el transcurso de varios meses, de repente se convirtió en un concepto que solo se aplica a la vacuna. "Esto todavía me sorprende", escribió. De hecho, es una flagrante corrupción de la ciencia.

En una página para pacientes de JAMA 2020 sobre inmunidad colectiva, el Dr. Angel Desai, editor asociado de JAMA Network Open, y Maimuna Majumder, Ph.D., del Boston Children's Hospital, Harvard Medical School, explican que la inmunidad colectiva se podría lograr por medio de la **infección natural** y recuperación, como siempre ha sido el caso:

"La inmunidad colectiva se puede lograr por medio de la infección, recuperación o la vacuna. Lograr la inmunidad colectiva a través de la infección depende de que suficientes personas estén infectadas con la enfermedad y se recuperen de ella, y en ese proceso desarrollan anticuerpos contra futuras infecciones".

El consejo de la OMS es muy cambiante

Quizás recuerde que, en los primeros días de la pandemia, no se recomendaban los cubrebocas. En febrero de 2020, Christine Francis, consultora para la prevención y el control de infecciones en la sede de la OMS, apareció en un video donde sostenía un cubrebocas desechable.

Ella dijo: "Los cubrebocas como este no pueden protegerlo contra el nuevo coronavirus cuando se usan solos. La OMS solo recomienda el uso de cubrebocas en casos específicos".

Esos casos específicos incluyen tos, fiebre o dificultad para respirar. En otras palabras, si está enfermo y presenta síntomas. "Si no tiene estos síntomas, no tiene que usar cubrebocas porque no hay evidencia de que protejan a las personas que no están enfermas", continuó.

En marzo de 2020, el Director General de Salud Pública de los Estados Unidos accedió de forma pública y tuiteó un mensaje que decía: "En serio, ¡DEJEN DE COMPRAR CUBREBOCAS!" y todavía dice que no son efectivos para evitar que las personas contraigan el coronavirus.

Para el 31 de marzo de 2020, la OMS desaconsejaba el uso de cubrebocas para personas asintomáticas, y afirmaba que "no había evidencia" de que dicho uso previniera la transmisión del COVID-19.

Y el 6 de junio de 2020, la retórica cambió. La OMS citó "evidencia en evolución" y revirtió su recomendación, Tedros Adhanom Ghebreyesus, director general de la OMS les aconsejó a los gobiernos que alentaran a las personas a usar cubrebocas donde hubiera una transmisión generalizada y el distanciamiento físico fuera difícil.

Otro ejemplo de cómo la OMS cambió convenientemente verdades anteriores para adaptarse a su plan ocurrió en junio de 2020. Durante una conferencia de prensa, Maria Van Kerkhove, líder técnica de la OMS para la pandemia de COVID-19, dejó muy claro que las personas que tienen COVID-19 sin síntomas **"rara vez" transmiten la enfermedad** a los demás. En un cambio radical, la OMS retracto la declaración un día despué.

El 9 de junio de 2020, el Dr. Mike Ryan, director ejecutivo del programa de emergencias de la OMS, retrocedió la declaración de Van Kerkhove y dijo que los comentarios fueron "malinterpretados o tal vez no utilizamos las palabras más elegantes para explicar eso".

La **propagación asintomática** es la única razón por la que tiene sentido el confinamiento y el uso del cubrebocas. Durante meses, los funcionarios de salud han creado el mito de la propagación asintomática para aumentar el miedo. Un estudio histórico que involucró a 9 899 828 millones de residentes de Wuhan, China, publicado en Nature Communications, no encontró ningún caso de transmisión asintomática.

Vivimos en un mundo de cabeza

En el transcurso de los últimos años, y en algunos casos en los últimos meses, las definiciones antiguas de pandemias, vacunas e inmunidad colectiva han cambiado para encajar con la nueva narrativa que elaboran los funcionarios de salud pública y los principales medios de comunicación.

En muchos sentidos, vive en una niebla de guerra en este momento: una **niebla de guerra del COVID** - según Jeffrey Tucker, director editorial del Instituto Americano de Investigaciones Económicas (AIER por sus siglas en inglés).

Durante una niebla así, "a menudo no está claro quién toma las decisiones, por qué y cuáles son las relaciones entre las estrategias y los objetivos. Incluso la lógica puede volverse incomprensible ya que la frustración y la desorientación desplazan la claridad y la racionalidad". Ver a través de la niebla es el primer paso para salir ileso de la batalla.

https://articulos.mercola.com/sitios/articulos/archivo/2021/03/25/oms-definicion-pandemia.aspx

OMS (Organización Mundial de la Salud) viola a la ciencia al cambiar el significado de inmunidad colectiva o de "rebaño"

Eduardo Ángel Yahbes   Médico MN 30101

En junio de 2020 la OMS modificó la definición de inmunidad colectiva afirmando que la única forma de lograrla es mediante la vacunación. Por supuesto que por ahora ninguna otra institución médica de control como el CDC, coinciden con esto

La evidencia científica establece que la inmunidad colectiva acontece cuando suficientes personas adquieren inmunidad a un determinado agente infeccioso, por haber padecido la enfermedad previamente. Lo que se extendió como posibilidad para las vacunaciones.

Decir que la única forma de lograr inmunidad colectiva es por vacunación suena absolutamente falso. Esto sólo apunta a la vacunación compulsiva, sobre todo para Covid-19 a nivel masivo, junto con elementos de seguimiento y rastreo del estado vacunal a lo que se suma la vigilancia biométrica. Recordemos los consejos del "médico del mundo" Bill Gates, de que es necesario incrustar en nuestros cuerpos elementos que permitan esta posibilidad. Ver tatuajes de puntos cuánticos de tinta invisible del Science Translational Medicine. Y también la vigilancia de cada aspecto de nuestras vidas, incluyendo el manejo de nuestro dinero.

La inmunidad colectiva lograda de manera natural suele ser de por vida para la inmensa mayoría de las enfermedades infectocontagiosas. En cambio la inmunidad lograda por las vacunas adolece de una falla primaria: no todos generan inmunidad específica y falla secundaria: para quienes la desarrollan es limitada en el tiempo. Teniendo en cuenta que las revacunaciones generan un tiempo menor de inmunidad comparado con las anteriores vacunas recibidas.

El otro aspecto a tener en cuenta es el llamado Pecado Original Antigénico. Se debe a que el organismo reacciona frente a una infección de un germen mutado como si fuese atacado por un germen igual al programado por la vacuna. Lo cual para el caso de virosis puede ser perjudicial al favorecer la ADE o enfermedad incrementada por anticuerpos. Por el contario la enfermedad natural genera inmunidad que puede abarcar gérmenes mutados. Por otra parte la inmunidad de memoria por la vía de administración, suele ubicarse en el organismo en lugares diferentes a la vía de contagio habitual.

Los brotes epidémicos de variadas enfermedades infectocontagiosas que se presentan en poblaciones vacunadas y revacunadas hasta casi un 100% evidencian lo que afirmamos.

El Dr. Gregory Poland admite que el sarampión se ha convertido en una enfermedad de vacunados.

Se producen mayor proporción de tos convulsa en poblaciones vacunadas.

Las vacunaciones orales de Polio llevadas a cabo por la Fundación Bill y Melinda Gates han incrementado los casos de parálisis flácida aguda.

Hay mayor incidencia de meningitis en poblaciones vacunadas

Se siguen viendo brotes de varicela y de paperas en poblaciones vacunadas.

Se ha demostrado que la vacuna BCG no es capaz de prevenir la tuberculosis en estudios realizados en India.

Consideramos que siendo la OMS un organismo dependiente financieramente de los laboratorios farmacéuticos tiene conflicto de intereses para emitir opiniones validadas científicamente. No debería emitir opiniones ni recomendaciones mientras persiste esta anomalía.

WHO (Accidentally) Confirms Covid is No More Dangerous Than Flu

Head of Health Emergencies Program "best estimates" put IFR at 0.14%

Kit Knightly

Dr Michael J. Ryan
EXECUTIVE DIRECTOR
WHO Health Emergencies Programme
Dr Tedros Adhanom Ghebreyesus
WHO DIRECTOR-GENERAL
Dr Maria Van Kerkhove
TECHNICAL LEAD
WHO Health Emergencies Programme
World Health Organization

The World Health Organization has finally confirmed what we (and many experts and studies) have been saying for months – the coronavirus is no more deadly or dangerous than seasonal flu.

The WHO's top brass made this announcement **during a special session of the WHO's 34-member executive board** on Monday October 5th, it's just nobody seemed to really understand it.

In fact, they didn't seem to completely understand it themselves.

At the session. Dr Michael Ryan, the WHO's Head of Emergencies revealed that they believe roughly 10% of the world has been infected with Sars-Cov-2. This is their "best estimate", and a huge increase over the number of officially recognised cases (around 35 million).

Dr. Margaret Harris, a WHO spokeswoman, later confirmed the figure, stating it was based on the average results of all the broad **seroprevalence studies** done around the world.

As much as the WHO were attempting to spin this as a bad thing – Dr Ryan even said it means *"the vast majority of the world remains at risk."* – it's actually good news. And confirms, once more, that the virus is nothing like as deadly as everyone predicted.

The global population is roughly **7.8 billion people**, if 10% have been infected that is 780 million cases. The global death toll currently attributed to Sars-Cov-2 infections is **1,061,539**.

That's an infection fatality rate of roughly or 0.14%. Right in line with seasonal flu and the predictions of many experts from all around the world.

0.14% is over 24 times LOWER than the WHO's "provisional figure" of **3.4% back in March**. This figure was used in the models which were used to justify lockdowns and other draconian policies.

In fact, given the **over-reporting of alleged Covid death**s, the IFR is likely even lower than 0.14%, and could show Covid to be much less dangerous than flu.

None of the mainstream press picked up on this. Though **many outlets** reported **Dr. Ryan's words**, they all attempted to make it a scary headline and spread more panic.

Apparently neither they, nor the WHO, were capable of doing the simple maths that shows us this is good news. And that the Covid sceptics have been right all along.

UPDATE 9/10/20: In the interest of thoroughness, a desire to rely on primary sources, and not depending purely on mainstream sources (which may remove or amend articles), I decided to find the actual video of Dr Ryan's remarks.

For some reason, although this was an important WHO meeting during an allegedly hyper-serious pandemic, the video is hard to find. The only place you are able to see it is the WHO's own website, and even then you have to scrub through almost 6 hours of footage. Well, I did that, and you are welcome.

You can't embed the WHO's stream, but I can tell you to go to **this page**, click "Session 1" and skip to 1:01:33 to hear the exact quote:

Our current best estimates tell us that about ten percent of the global population may have been infected by this virus. This varies depending on country, it varies from urban to rural, it varies between different groups."

https://off-guardian.org/2020/10/08/who-accidentally-confirms-covid-is-no-more-dangerous-than-flu/

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Infection fatality rate of COVID-19 inferred from seroprevalence data

John P A Ioannidis[a]

[a] Meta-Research Innovation Center at Stanford (METRICS), Stanford University, 1265 Welch Road, Stanford, California 94305, United States of America.

Correspondence to John P A Ioannidis (email: jioannid@stanford.edu).

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Abstract

Objective To estimate the infection fatality rate of coronavirus disease 2019 (COVID-19) from seroprevalence data.

Methods I searched PubMed and preprint servers for COVID-19 seroprevalence studies with a sample size ≥ 500 as of 9 September, 2020. I also retrieved additional results of national studies from preliminary press releases and reports. I assessed the studies for design features and seroprevalence estimates. I estimated the infection fatality rate for each study by dividing the number of COVID-19 deaths by the number of people estimated to be infected in each region. I corrected for the number of antibody types tested (immunoglobin, IgG, IgM, IgA).

Results I included 61 studies (74 estimates) and eight preliminary national estimates. Seroprevalence estimates ranged from 0.02% to 53.40%. Infection fatality rates ranged from 0.00% to 1.63%, corrected values from 0.00% to 1.54%. Across 51 locations, the median COVID-19 infection fatality rate was 0.27% (corrected 0.23%): the rate was 0.09% in locations with COVID-19 population mortality rates less than the global average (< 118 deaths/million), 0.20% in locations with 118–500 COVID-19 deaths/million people and 0.57% in locations with > 500 COVID-19 deaths/million people. In people < 70 years, infection fatality rates ranged from 0.00% to 0.31% with crude and corrected medians of 0.05%.

Conclusion The infection fatality rate of COVID-19 can vary substantially across different locations and this may reflect differences in population age structure and case-mix of infected and deceased patients and other factors. The inferred infection fatality rates tended to be much lower than estimates made earlier in the pandemic.

Introduction

The infection fatality rate, the probability of dying for a person who is infected, is one of the most important features of the coronavirus disease 2019 (COVID-19) pandemic. The expected total mortality burden of COVID-19 is directly related to the infection fatality rate. Moreover,

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justification for various non-pharmacological public health interventions depends on the infection fatality rate. Some stringent interventions that potentially also result in more noticeable collateral harms[1] may be considered appropriate, if the infection fatality rate is high. Conversely, the same measures may fall short of acceptable risk–benefit thresholds, if the infection fatality rate is low.

Early data from China suggested a 3.4% case fatality rate[2] and that asymptomatic infections were uncommon,[3] thus the case fatality rate and infection fatality rate would be about the same. Mathematical models have suggested that 40–81% of the world population could be infected,[4,5] and have lowered the infection fatality rate to 1.0% or 0.9%.[5,6] Since March 2020, many studies have estimated the spread of the virus causing COVID-19 – severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) – in various locations by evaluating seroprevalence. I used the prevalence data from these studies to infer estimates of the COVID-19 infection fatality rate.

Methods

Seroprevalence studies

The input data for calculations of infection fatality rate were studies on the seroprevalence of COVID-19 done in the general population, or in samples that might approximately represent the general population (e.g. with proper reweighting), that had been published in peer-reviewed journals or as preprints (irrespective of language) as of 9 September 2020. I considered only studies with at least 500 assessed samples because smaller data sets would result in large uncertainty for any calculations based on these data. I included studies that made seroprevalence assessments at different time intervals if at least one time interval assessment had a sample size of at least 500 participants. If there were different eligible time intervals, I selected the one with the highest seroprevalence, since seroprevalence may decrease over time as antibody titres decrease. I excluded studies with data collected for more than a month that could not be broken into at least one eligible time interval less than one month duration because it would not be possible to estimate a point seroprevalence reliably. Studies were eligible regardless of the exact age range of participants included, but I excluded studies with only children.

I also examined results from national studies from preliminary press releases and reports whenever a country had no other data presented in published papers of preprints. This inclusion allowed these countries to be represented, but information was less complete than information in published papers or preprints and thus requires caution.

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I included studies on blood donors, although they may underestimate seroprevalence and overestimate infection fatality rate because of the healthy volunteer effect. I excluded studies on health-care workers, since this group is at a potentially high exposure risk, which may result in seroprevalence estimates much higher than the general population and thus an improbably low infection fatality rate. Similarly, I also excluded studies on communities (e.g. shelters or religious or other shared-living communities). Studies were eligible regardless of whether they aimed to evaluate seroprevalence in large or small regions, provided that the population of reference in the region was at least 5000 people.

I searched PubMed® (LitCOVID), and medRxiv, bioRxiv and Research Square using the terms "seroprevalence" OR "antibodies" with continuous updates. I made the first search in early May and did monthly updates, with the last update on 9 September, 2020. I contacted field experts to retrieve any important studies that may have been missed.

From each study, I extracted information on location, recruitment and sampling strategy, dates of sample collection, sample size, types of antibody measured (immunoglobulin G (IgG), IgM and IgA), the estimated crude seroprevalence (positive samples divided by all samples tested), adjusted seroprevalence and the factors that the authors considered for adjustment.

Inferred infection fatality rate

If a study did not cover an entire country, I collected information on the population of the relevant location from the paper or recent census data so as to approximate as much as possible the relevant catchment area (e.g. region(s) or county(ies)). Some studies targeted specific age groups (e.g. excluding elderly people and/or excluding children) and some estimated numbers of people infected in the population based on specific age groups. For consistency, I used the entire population (all ages) and, separately, the population 0–70 years to estimate numbers of infected people. I assumed that the seroprevalence would be similar in different age groups, but I also recorded any significant differences in seroprevalence across age strata so as to examine the validity of this assumption.

I calculated the number of infected people by multiplying the relevant population size and the adjusted estimate of seroprevalence. If a study did not give an adjusted seroprevalence estimate, I used the unadjusted seroprevalence instead. When seroprevalence estimates with different adjustments were available, I selected the analysis with largest adjustment. The factors adjusted for included COVID-19 test performance, sampling design, and other factors such as age, sex, clustering effects or socioeconomic factors. I did not adjust for specificity in test performance when positive antibody results were already validated by a different method.

For the number of COVID-19 deaths, I chose the number of deaths accumulated until the date 1 week after the midpoint of the study period (or the date closest to this that had available data) – unless the authors of the study had strong arguments to choose some other time point or approach. The 1-week lag accounts for different delays in developing antibodies versus dying from infection. The number of deaths is an approximation because it is not known when exactly each patient who died was infected. The 1-week cut-off after the study midpoint may underestimate deaths in places where patients are in hospital for a long time before death, and may overestimate deaths in places where patients die soon because of poor or even inappropriate care. Whether or not the health system became overloaded may also affect the number of deaths. Moreover, because of imperfect diagnostic documentation, COVID-19 deaths may have been both overcounted and undercounted in different locations and at different time points.

I calculated the inferred infection fatality rate by dividing the number of deaths by the number of infected people for the entire population, and separately for people < 70 years. I took the proportion of COVID-19 deaths that occurred in people < 70 years old from situational reports for the respective locations that I retrieved at the time I identified the seroprevalence studies. I also calculated a corrected infection fatality rate to try and account for the fact that only one or two types of antibodies (among IgG, IgM, IgA) might have been used. I corrected seroprevalence upwards (and inferred infection fatality rate downwards) by one tenth of its value if a study did not measure IgM and similarly if IgA was not measured. This correction is reasonable based on some early evidence,[7] although there is uncertainty about the exact correction factor.

Data synthesis

The estimates of the infection fatality rate across all locations showed great heterogeneity with I^2 exceeding 99.9%; thus, a meta-analysis would be inappropriate to report across all locations. Quantitative synthesis with meta-analysis across all locations would also be misleading since locations with high COVID-19 seroprevalence would tend to carry more weight than locations with low seroprevalence. Furthermore, locations with more studies (typically those that have attracted more attention because of high death tolls and thus high infection fatality rates) would be represented multiple times in the calculations. In addition, poorly conducted studies with fewer adjustments would get more weight because of spuriously narrower confidence intervals than more rigorous studies with more careful adjustments which allow for more uncertainty. Finally, with a highly skewed distribution of the infection fatality rate and with large between-study heterogeneity, typical random effects models would produce an incorrectly high summary infection fatality rate that approximates the mean of the study-specific estimates (also strongly influenced by high-mortality locations where more studies have been done); for such a skewed distribution, the median is more appropriate.

Therefore, in a first step, I grouped estimates of the infection fatality rate from studies in the same country (or for the United States of America, the same state) together and calculated a single infection fatality rate for that location, weighting the study-specific infection fatality rates by the sample size of each study. This approach avoided inappropriately giving more weight to studies with higher seroprevalence estimates and those with seemingly narrower confidence intervals because of poor or no adjustments, while still giving more weight to larger studies. Then, I used the single summary estimate for each location to calculate the median of the distribution of location-specific infection fatality rate estimates. Finally, I explored whether the location-specific infection fatality rates were associated with the COVID-19 mortality rate in the population (COVID-19 deaths per million people) in each location as of 12 September 2020; this analysis allowed me to assess whether estimates of the infection fatality rate tended to be higher in locations with a higher burden of death from COVID-19.

Results

Seroprevalence studies

I retrieved 61 studies with 74 eligible estimates published either in the peer-reviewed literature or as preprints as of 9 September 2020.[8–68] Furthermore, I also considered another eight preliminary national estimates.[69–76] This search yielded a total of 82 eligible estimates (Fig. 1).

The studies varied substantially in sampling and recruitment designs (Table 1; available at: http://www.who.int/bulletin/volumes/##/##/##-######). Of the 61 studies, 24 studies[8,10,16,17,20,22,25,33,34,36,37,42,46–49,52–54,61,63,65,68] explicitly aimed for random sampling from the general population. In principle, random sampling is a stronger design. However, even then, people who cannot be reached (e.g. by email or telephone or even by visiting them at a house location) will not be recruited, and these vulnerable populations are likely to be missed. Moreover, several such studies[8,10,16,37,42] focused on geographical locations with high numbers of deaths, higher than other locations in the same city or country, and this emphasis would tend to select eventually for a higher infection fatality rate on average.

Eleven studies assessed blood donors,[12,15,18,24,28,31,41,44,45,55,60] which might underestimate COVID-19 seroprevalence in the general population. For example, 200 blood donors in Oise, France showed 3.00% seroprevalence, while the seroprevalence was 25.87% (171/661) in pupils, siblings, parents, teachers and staff at a high school with a cluster of cases in the same area; the true population seroprevalence may be between these two values.[13]

For other studies, healthy volunteer bias[19] may underestimate seroprevalence, attracting people with symptoms[26] may overestimate seroprevalence, and studies of employees,[14,21,25,32,66] grocery store clients[23] or patient cohorts[11,14,27–30,36,38,40,50,51,56,59,62,64,67] risk sampling bias in an unpredictable direction.

All the studies tested for IgG antibodies but only about half also assessed IgM and few assessed IgA. Only seven studies assessed all three types of antibodies and/or used pan-Ig antibodies. The ratio of people sampled versus the total population of the region was more than 1:1000 in 20 studies (Table 2; available at: http://www.who.int/bulletin/volumes/##/##/##-######).

Seroprevalence estimates

Seroprevalence for the infection ranged from 0.02% to 53.40% (58.40% in the slum sub-population in Mumbai; Table 3). Studies varied considerably depending on whether or not they tried to adjust their estimates for test performance, sampling (to get closer to a more representative sample), clustering (e.g. when including household members) and other factors. The adjusted seroprevalence occasionally differed substantially from the unadjusted value. In studies that used samples from multiple locations, between-location heterogeneity was seen (e.g. 0.00–25.00% across 133 Brazilian cities).[25]

Inferred infection fatality rate

Inferred infection fatality rate estimates varied from 0.00% to 1.63% (Table 4). Corrected values also varied considerably (0.00–1.54%).

For 15 locations, more than one estimate of the infection fatality rate was available and thus I could compare the infection fatality rate from different studies evaluating the same location. The estimates of infection fatality rate tended to be more homogeneous within each location, while they differed markedly across locations (Fig. 2). Within the same location, infection fatality rate estimates tend to have only small differences, even though it is possible that different areas within the same location may also have real differences in infection fatality rate. France is one exception where differences are large, but both estimates come from population studies of outbreaks from schools and thus may not provide good estimates of population seroprevalence and may lead to an underestimated infection fatality rate.

I used summary estimates weighted for sample size to generate a single estimate for each location. Data were available for 51 different locations (including the inferred infection fatality rates from the eight preliminary additional national estimates in Table 5).

The median infection fatality rate across all 51 locations was 0.27% (corrected 0.23%). Most data came from locations with high death tolls from COVID-19 and 32 of the locations had a population mortality rate (COVID-19 deaths per million population) higher than the global average (118 deaths from COVID-19 per million as of 12 September 2020;[79] Fig. 3). Uncorrected estimates of the infection fatality rate of COVID-19 ranged from 0.01% to 0.67% (median 0.10%) across the 19 locations with a population mortality rate for COVID-19 lower than the global average, from 0.07% to 0.73% (median 0.20%) across 17 locations with population mortality rate higher than the global average but lower than 500 COVID-19 deaths per million, and from 0.20% to 1.63% (median 0.71%) across 15 locations with more than 500 COVID-19 deaths per million. The corrected estimates of the median infection fatality rate were 0.09%, 0.20% and 0.57%, respectively, for the three location groups.

For people < 70 years old, the infection fatality rate of COVId-19 across 40 locations with available data ranged from 0.00% to 0.31% (median 0.05%); the corrected values were similar.

Discussion

The infection fatality rate is not a fixed physical constant and it can vary substantially across locations, depending on the population structure, the case-mix of infected and deceased individuals and other, local factors. The studies analysed here represent 82 different estimates of the infection fatality rate of COVID-19, but they are not fully representative of all countries and locations around the world. Most of the studies are from locations with overall COVID-19 mortality rates that are higher than the global average. The inferred median infection fatality rate in locations with a COVID-19 mortality rate lower than the global average is low (0.09%). If one could sample equally from all locations globally, the median infection fatality rate might be even substantially lower than the 0.23% observed in my analysis.

COVID-19 has a very steep age gradient for risk of death.[80] Moreover, many, and in some cases most, deaths in European countries that have had large numbers of cases and deaths[81] and in the USA[82] occurred in nursing homes. Locations with many nursing home deaths may have high estimates of the infection fatality rate, but the infection fatality rate would still be low among non-elderly, non-debilitated people.

Within China, the much higher infection fatality rate estimates in Wuhan compared with other areas of the country may reflect widespread nosocomial infections,[83] as well as unfamiliarity with how to manage the infection as the first location that had to deal with COVID-19. The very many deaths in nursing homes, nosocomial infections and overwhelmed hospitals may also explain the high number of fatalities in specific locations in Italy[84] and New York and neighbouring states.[23,27,35,56] Poor decisions (e.g. sending COVID-19 patients to nursing homes), poor management (e.g. unnecessary mechanical ventilation) and hydroxychloroquine may also have contributed to worse outcomes. High levels of congestion (e.g. in busy public transport systems) may also have exposed many people to high infectious loads and, thus, perhaps more severe disease. A more aggressive viral clade has also been speculated.[85] The infection fatality rate may be very high among disadvantaged populations and settings with a combination of factors predisposing to higher fatalities.[37]

Very low infection fatality rates seem common in Asian countries.[8,11,29,48,49,51,59,61,67] A younger population in these countries (excluding Japan), previous immunity from exposure to other coronaviruses, genetic differences, hygiene etiquette, lower infectious load and other unknown factors may explain these low rates. The infection fatality rate is low also in low-income countries in both Asia and Africa,[44,49,66,67] perhaps reflecting the young age-structure. However, comorbidities, poverty, frailty (e.g. malnutrition) and congested urban living circumstances may have an adverse effect on risk and thus increase infection fatality rate.

Antibody titres may decline with time[10,28,32,86,87] and this would give falsely low prevalence estimates. I considered the maximum seroprevalence estimate when multiple repeated measurements at different time points were available, but even then some of this decline cannot be fully accounted for. With four exceptions,[10,28,32,51] the maximum seroprevalence value was at the latest time point.

Positive controls for the antibody assays used were typically symptomatic patients with positive polymerase chain reaction tests. Symptomatic patients may be more likely to develop antibodies.[87–91] Since seroprevalence studies specifically try to reveal undiagnosed asymptomatic and mildly symptomatic infections, a lower sensitivity for these mild infections could lead to substantial underestimates of the number of infected people and overestimate of the inferred infection fatality rate.

A main issue with seroprevalence studies is whether they offer a representative picture of the population in the assessed region. A generic problem is that vulnerable people at high risk of infection and/or death may be more difficult to recruit in survey-type studies. COVID-19 infection is particularly widespread and/or lethal in nursing homes, in homeless people, in prisons and in disadvantaged minorities.[92] Most of these populations are very difficult, or even impossible, to reach and sample and they are probably under-represented to various degrees (or even entirely missed) in surveys. This sampling obstacle would result in underestimating the seroprevalence and overestimating infection fatality rate.

In principle, adjusted seroprevalence values may be closer to the true estimate, but the adjustments show that each study alone may have unavoidable uncertainty and fluctuation, depending on the type of analysis chosen. Furthermore, my corrected infection fatality rate estimates try to account for undercounting of infected people when not all three antibodies (IgG, IgM and IgA) were assessed. However, the magnitude of the correction is uncertain and may vary in different circumstances. An unknown proportion of people may have responded to the virus using immune mechanisms (mucosal, innate, cellular) without generating any serum antibodies.[93–97]

A limitation of this analysis is that several studies included have not yet been fully peer-reviewed and some are still ongoing. Moreover, despite efforts made by seroprevalence studies to generate estimates applicable to the general population, representativeness is difficult to ensure, even for the most rigorous studies and despite adjustments made. Estimating a single infection fatality rate value for a whole country or state can be misleading, when there is often huge variation in the population mixing patterns and pockets of high or low mortality. Furthermore, many studies have evaluated people within restricted age ranges, and the age groups that are not included may differ in seroprevalence. Statistically significant, modest differences in seroprevalence across some age groups have been observed in several studies.[10,13,15,23,27,36,38]

Lower values have been seen in young children and higher values in adolescents and young adults, but these patterns are inconsistent and not strong enough to suggest major differences extrapolating across age groups.

Acknowledging these limitations, based on the currently available data, one may project that over half a billion people have been infected as of 12 September, 2020, far more than the approximately 29 million documented laboratory-confirmed cases. Most locations probably have an infection fatality rate less than 0.20% and with appropriate, precise non-pharmacological measures that selectively try to protect high-risk vulnerable populations and settings, the infection fatality rate may be brought even lower.

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Competing interests:

I am a co-author (not principal investigator) of one of the seroprevalence studies.

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Table 1. **Eligible seroprevalence studies on COVID-19 published or deposited as preprints as of 9 September 2020: dates, sampling and recruitment**

Author	Country (location)	Dates	Sampling and recruitment
Figar et al.[47]	Argentina (Barrio Padre Mugica)	10–26 June	Probabilistic sampling of a slum neighbourhood, sampling from people 14 years or older across households
Herzog et al.[38]	Belgium	30 March–5 April and 20–26 April	Residual sera from 10 private diagnostic laboratories in Belgium, with fixed numbers per age group, region and periodical sampling, and stratified by sex
Hallal et al.[25]	Brazil	15–22 May	Sampling from 133 cities (the main city in each region), selecting 25 census tracts with probability proportionate to size in each sentinel city, and 10 households at random in each tract. Aiming for 250 participants per city
Gomes et al.[34]	Brazil (Espirito Santo)	13–15 May	Cross-section of major municipalities with houses as the sampling units
Da Silva et al.[68]	Brazil (Maranhao)	27 July–8 August	Three-stage cluster sampling stratified by four state regions in the state of Maranhao; the estimates took clustering, stratification and non-response into account
Amorim Filho et al.[41]	Brazil (Rio de Janeiro)	14–27 April (eligible: 24–27 April)	Blood donors without flulike symptoms within 30 days of donation; had close contact with suspected or confirmed COVID-19 cases in the 30 days before donation; or had travelled abroad in the past 30 days
Silveira et al.[17]	Brazil (Rio Grande do Sul)	9–11 May (third round, after 11–13 April, and 25–27 April)	Multistage probability sampling in each of nine cities to select 500 households, from which one member was randomly chosen for testing
Tess et al.[42]	Brazil (Sao Paulo)	4–12 May	Randomly selected adults and their cohabitants sampled from six districts of Sao Paulo City with high numbers of cases
Skowronski et al.[50]	Canada (British Columbia)	15–27 May (after baseline in 5–13 March)	Specimens from patients attending one of about 80 diagnostic service centres of the only outpatient laboratory network in the Lower Mainland
Torres et al.[43]	Chile (Vitacura)	4–19 May	Classroom stratified sample of children and all staff in a community placed on quarantine after school outbreak
Chang et al.[55]	China	January–April weekly: 3–23 February (Wuhan); 24 February–15 March (Shenzhen); 10 February–1 March (Shijiazhuang)	38 144 healthy blood donors in Wuhan, Shenzhen and Shijiazhuang who met the criteria for blood donation during the COVID-19 pandemic in China
Wu et al.[14]	China (Wuhan)	3–15 April	People applying for a permission to resume work (*n* = 1 021) and hospitalized patients (*n* = 381)
Ling et al.[32]	China (Wuhan)	26 March–28 April	Age 16–64 years, going back to work, with no fever, headache or other symptoms of COVID-19
Xu et al.[60]	China (Guangzhou)	23 March–2 April	Healthy blood donors in Guangzhou

Xu et al.[40]	China (several regions)	30 March–10 April	Voluntary participation by public call for haemodialysis patients ($n = 979$ in Zingzhou, Ubei and $n = 563$ in Guangzhou/Foshun, Guangdong) and outpatients in Chingqing ($n = 993$), and community residents in Chengdu, Sichuan ($n = 9\,442$), and required testing for factory workers in Guangzhou, Guandong ($n = 442$)
Jerkovic et al.[26]	Croatia	23–28 April	DIV Group factory workers in Split and Sibenik-Knin invited for voluntary testing
Erikstrup et al.[12]	Denmark	6 April–3 May	All Danish blood donors aged 17–69 years giving blood. Blood donors are healthy and must comply with strict eligibility criteria; they must self-defer for two weeks if they develop fever with upper respiratory symptoms
Petersen et al.[52]	Denmark (Faroe Islands)	27 April–1 May	1500 randomly selected residents invited to participate, samples collected from 1 075
Fontanet et al.[39]	France (Crepy-en-Valois)	28–30 April	Pupils, their parents and relatives, and staff of primary schools exposed to SARS-CoV-2 in February and March 2020 in a city north of Paris
Fontanet et al.[13]	France (Oise)	30 March–4 April	Pupils, their parents and siblings, as well as teachers and non-teaching staff of a high-school
Streeck et al.[16]	Germany (Gangelt)	30 March–6 April	600 adults with different surnames in Gangelt were randomly selected; all household members were asked to participate in the study
Kraehling et al.[21]	Germany (Frankfurt)	6–14 April	Employees of Infraserv Höchst, a large industrial site operator in Frankfurt am Main. No exclusion criteria
Bogogiannidou et al.[62]	Greece	March and April (April data used)	Leftover blood samples collected from a nationwide laboratory network, including both private and public hospital laboratories (27 laboratories in total)
Merkely et al.[57]	Hungary	1–16 May	Representative sample ($n = 17\,787$) of the Hungarian population ≥ 14 years living in private households (8 283 810)
Gudbjatsson et al.[58]	Iceland	Several cohorts between April and June[a]	30 576 people in Iceland, including those documented to be infected, those quarantined and people not known to have been exposed.
Malani et al.[61]	India (Mumbai)	29 June–19 July	Geographically-spaced community sampling of households, one individual per household was tested in slum and non-slum communities in three wards, one each from the three main zones of Mumbai
Khan et al.[67]	India (Srinagar)	1–15 July	Adults (> 18 years) who visited selected hospitals across the Srinagar District
Shakiba et al.[8]	Islamic Republic of Iran (Guilan)	April (until 21 April)	Population-based cluster random sampling design through telephone call invitation, household-based
Fiore et al.[31]	Italy (Apulia)	1–31 May	Blood donors 18–65 years old free of recent symptoms possibly related to COVID-19, no close contact with confirmed cases, symptom-free in the preceding 14 days, no contact with suspected cases
Doi et al.[11]	Japan (Kobe)	31 March–7 April	Randomly selected patients who visited outpatient clinics and received blood testing for any reason. Patients who visited the emergency department or the designated fever consultation service were excluded
Takita et al.[29]	Japan (Tokyo)	21 April–20 May	Two community clinics in the main railway stations in Tokyo (Navitas Clinic Shinjuku and Tachikawa)

Nawa et al.[48]	Japan (Utsunomiya City)	14 June–5 July	Invitations enclosed with a questionnaire were sent to 2 290 people in 1 000 households randomly selected from Utsunomiya City's basic resident registry; 742 completed the study
Uyoga et al.[44]	Kenya	30 April–16 June (~90% of samples in last 30 days)	Residual blood donor serum samples from donors 16–65 years in four sites (Mombasa, Nairobi, Eldoret and Kisumu)
Snoeck et al.[20]	Luxembourg	16 April–5 May	Representative sample (no details how ensured), 1 807 of 2000 contacted provided data, were < 79 years and had serology results
Slot et al.[15]	Netherlands	1–15 April	Blood donors. Donors must be completely healthy, but they may have been ill in the past, provided that they recovered at least 2 weeks before
Westerhuis et al.[64]	Netherlands (Rotterdam)	Early March and early April	Left-over plasma samples from patients of nine age categories in Erasmus Medical Center in Rotterdam: 879 samples in early March and 729 in early April)
Nisar et al.[49]	Pakistan (Karachi)	25 June–11 July (after baseline on 15–25 April)	Cross-sectional household surveys in a low- (district Malir) and high-transmission (district East) area of Karachi with households selected using simple random sampling (Malir) and systematic random sampling (East)
Javed et al.[66]	Pakistan (urban Karachi, Lahore, Multan, Peshawar and Quetta)	06-Jul	Adult, working population aged 18–65 years, recruited from dense, urban workplaces including factories, businesses, restaurants, media houses, schools, banks, hospitals (health-care providers), and from families of positive cases in cities in Pakistan
Abu Raddad et al.[51]	Qatar	12 May–12 July (highest seroprevalence on 12–31 May)	Convenience sample of residual blood specimens collected for routine clinical screening or clinical management from 32 970 outpatient and inpatient departments for a variety of health conditions (*n* = 937 in 12–31 May)
Noh et al.[59]	Republic of Korea	25–29 May	Outpatients who visited two hospitals in south-west Seoul which serve six administrative areas
Pollan et al.[36]	Spain	27 April–11 May	35 883 households selected from municipal rolls using two-stage random sampling stratified by province and municipality size, with all residents invited to participate (75.1% of all contacted individuals participated)
Crovetto et al.[30]	Spain (Barcelona)	14 April–5 May	Consecutive pregnant women for first trimester screening or delivery in two hospitals
Stringhini et al.[10]	Switzerland (Geneva)	6 April–9 May (5 consecutive weeks)	Randomly selected previous participants of the Bus Santé study with an email (or telephone contact, if email unavailable); participants were invited to bring all members of their household aged 5 years and older
Emmenegger et al.[28]	Switzerland (Zurich)	Prepandemic until June (patients) and May (blood donors)	Patients at the University Hospital of Zurich and blood donors in Zurich and Lucerne
Ward et al.[65]	United Kingdom (England)	20 June–13 July	Random population sample of 100 000 adults over 18 years
Thompson et al.[18]	United Kingdom (Scotland)	21–23 March	Blood donors. Donors should not have felt unwell in the past 14 days; some other deferrals also applied regarding travel and COVID-19 symptoms

Havers et al.[35]	USA (10 states)	23 March–1 April (Washington, Puget Sound and New York, New York City), 1–8 April (Louisiana), 5–10 April (Florida, south), 13–25 April (Pennsylvania, Philadelphia, metropolitan area), 20–26 April (Missouri), 23–27 April (California, San Francisco Bay Area), 20 April–3 May (Utah), 26 April–3 May (Connecticut), 30 April–12 May (Minnesota, Minneapolis)	Convenience samples using residual sera obtained for routine clinical testing (screening or management) by two commercial laboratory companies
Ng et al.[24]	USA (California, Bay Area)	March	1000 blood donors in diverse Bay Area locations (excluding those with self-reported symptoms or abnormal vital signs)
Sood[22]	USA (California, Los Angeles)	10–14 April	Proprietary database representative of the county. A random sample of these residents was invited, with quotas for enrolment for subgroups based on age, sex, race and ethnicity distribution
Chamie et al.[33]	USA (California, San Francisco)	25–28 April	United States census tract 022 901 population-dense area (58% Latin American) in San Francisco Mission district, expanded to neighbouring blocks on 28 April
Bendavid et al.[19]	USA (California, Santa Clara)	2–3 April	Facebook advertisement with additional targeting by zip code
Biggs et al.[53]	USA (Georgia, DeKalb and Fulton)	28 April–3 May	Two-stage cluster sampling design used to randomly select 30 census blocks in DeKalb county and 30 census blocks in Fulton county, with a target of seven participating households per census block
McLaughlin et al.[46]	USA (Idaho, Blaine county)	4–19 May	Volunteers who registered via a secure web link, using prestratification weighting to the population distribution by age and sex within each zip code
Bryan et al.[9]	USA (Idaho, Boise)	Late April	People from the Boise, Idaho metropolitan area, part of the Crush the Curve initiative
Menachemi et al.[54]	USA (Indiana)	25–29 April	Stratified random sampling among all persons aged ≥ 12 years using Indiana's 10 public health preparedness districts as sampling strata
Feehan et al.[63]	USA (Louisiana, Baton Rouge)	15–31 July	Representative sample in a method developed by Public Democracy

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Feehan et al.[37]	USA (Louisiana, Orleans and Jefferson Parish)	9–15 May	Pool of potential participants reflecting the demographics of the parishes was based on 50 characteristics, then a randomized subset of 150 000 people was selected, and 25 000 were approached with digital apps, and 2 640 were recruited
Rosenberg et al.[23]	USA (New York)	19–28 April	Convenience sample of people ≥ 18 years living in New York State, recruited consecutively on entering 99 grocery stores and through an in-store flyer
Meyers et al.[56]	USA (New York)	2–30 March (Columbia University Medical Center, New York City); 13–28 March (CareMount central laboratory)	Discarded clinical samples in Columbia Medical Center, New York City ($n = 814$ in 24 February–30 March, 742 of those in the period 2–30 March) and samples from CareMount central laboratory (960 samples on 13 and 14 March, 505 samples on 20/21 March, and 376 samples on 27/28 March) from its network of clinics in five counties north of New York City
Reifer et al.[27]	USA (New York, Brooklyn)	Early May	Patients seen in an urgent care facility in Brooklyn
Nesbitt et al.[45]	USA (Rhode Island)	27 April–11 May	Consecutive blood donors

COVID-19: coronavirus disease-19; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

[a] Sample collection time for some sub-cohorts may have exceeded 1 month, but more than half of the cases were already documented by polymerase chain reaction testing before any antibody testing and the last death occurred on 20 April.

Note: Some studies included additional data sets that did not fulfil the eligibility criteria (e.g. had sample size < 500 or were health-care workers) and they are not presented here.

Table 2. **Sample size, types of antibodies assessed and population size in the studies included to assess COVID-19 infection fatality rate, 2020**

Country (location)	Sample size[a], no.	Antibody	Population,[b] no.	% of population <70 years[c]
Argentina (Barrio Padre Mugica)[47]	873	IgG	49 983	99
Belgium[38]	3 391 (20–26 April)	IgG	11 589 623	86
Brazil (133 cities)[25]	24 995	IgG and IgM	74 656 499	94 (Brazil)
Brazil (Espirito Santo)[34]	4 608	IgG and IgM	4 018 650	94 (Brazil)
Brazil (Maranhao)[68]	3 156	IgG and IgM	7 114 598	92
Brazil (Rio de Janeiro), blood donors[41]	669 (24–27 April)	IgG and IgM	17 264 943	94 (Brazil)
Brazil (Rio Grande do Sul)[17]	4 500	IgG	11 377 239	91
Brazil (Sao Paulo)[42]	517	IgG and IgM	298 240 (6 districts)	94 (Brazil)
Canada (British Columbia)[50]	885	IgG, IgM and IgA	5 071 000	94
Chile (Vitacura)[43]	1 244	IgG and IgM	85 000	92 (Chile)
China, blood donors[55]				
Wuhan	930 (3–23 February)	IgG and IgM	11 210 000	93 (China)
Shenzhen	3 507 (24 February–15 March)	IgG and IgM	13 030 000	93 (China)
Shijiazhuang	6 455 (10 February–1 March)	IgG and IgM	11 030 000	93 (China)
China (Wuhan)[14]	1 401	IgG and IgM	11 080 000	93 (China)
China (Wuhan)[32]	1 196 (4–8 April)	IgG and IgM	11 080 000	93 (China)
China (Guangzhou), blood donors[60]	2 199	IgG, IgM and IgA	115 210 000 (Guangdong)	93 (China)
China (several regions)[40]				
Hubei (not Wuhan)	979	IgG and IgM	48 058 000	93 (China)
Chongqing	993	IgG and IgM	31 243 200	93 (China)
Sichuan	9 442	IgG and IgM	83 750 000	93 (China)
Guangdong	1 005	IgG and IgM	115 210 000	93 (China)
Croatia[26]	1 494	IgG and IgM	4 076 000	86
Denmark blood donors[12]	20 640	IgG and IgM	5 771 876	86
Denmark (Faroe Islands)[52]	1 075	IgG and IgM	52 428	88
France (Crepy-en-Valois)[39]	1 340	IgG	5 978 000 (Hauts-de-France)	89
France (Oise)[13]	661	IgG	5 978 000 (Hauts-de-France)	89
Germany (Gangelt)[16]	919	IgG and IgA	12 597	86
Germany (Frankfurt)[21]	1 000	IgG	2 681 000[d]	84 (Germany)
Greece[62]	6 586 (4 511 in April)	IgG	10 412 967	84
Hungary[57]	10 504	IgG (also had PCR)	9 657 451	88
Iceland[58]	30 576	Pan-Ig	366 854	90
India (Mumbai)[61]	6 904 (4 202 in slums, 2 702 not in slums)	IgG	1 414 917 (705 523 in slums, 709 394 in non-slums) in the 3 ward areas	98
India (Srinagar)[67]	2 906	IgG	1 500 000	97
Islamic Republic of Iran (Guilan)[8]	551	IgG and IgM	2 354 848	95
Italy (Apulia), blood donors[31]	909	IgG and /IgM	4 029 000	84
Japan (Kobe)[11]	1 000	IgG	1 518 870	79 (Japan)
Japan (Tokyo)[29]	1 071	IgG	13 902 077	79 (Japan)
Japan (Utsunomiya City)[48]	742	IgG	518 610	79 (Japan)
Kenya, blood donors[44]	3 098	IgG	47 564 296	99
Luxembourg[20]	1 807	IgG and IgA[e]	615 729	90
Netherlands blood donors[15]	7 361	IgG, IgM and IgA	17 097 123	86
Netherlands (Rotterdam)[64]	729 (early April)	IgG	17 097 123 (Netherlands)	86
Pakistan (Karachi)[49]	1 004	IgG and IgM	16 700 000	98 (Pakistan)
Pakistan (urban)[66]	24 210	IgG and IgM	79 000 000 (urban)	98

Qatar[51]	937	IgG	2 800 000	99
Republic of Korea[59]	1 500	IgG	2 667 341	90 (southern Republic of Korea)
Spain[36]	61 075	IgG	46 940 000	85
Spain (Barcelona)[30]	874	IgG, IgM and IgA	7 566 000 (Catalonia)	86
Switzerland (Geneva)[10]	577 (20–27 April)	IgG	500 000	88
Switzerland (Zurich)[28]	1 644 patients (1–15 April)	IgG	1 520 968 (Zurich canton)	88
Switzerland (Zurich)[28]	1 640 blood donors (May)	IgG	1 930 525 (Zurich and Lucerne)	88
United Kingdom (England)[65]	109 076	IgG	56 287 000	86
United Kingdom (Scotland), blood donors[18]	500	IgG	5 400 000	88
USA (10 states)[35]				
Washington, Puget Sound	3 264	Pan-Ig	4 273 548	90 (Washington)
Utah	1 132	Pan-Ig	3 282 120	92
New York, New York City	2 482	Pan-Ig	9 260 870	89
Missouri	1 882	Pan-Ig	6 110 800	88
Florida, south	1 742	Pan-Ig	6 345 345	86 (Florida)
Connecticut	1 431	Pan-Ig	3 562 989	88
Louisiana	1 184	Pan-Ig	4 644 049	92
California, San Francisco Bay	1 224	Pan-Ig	2 173 082	90
Pennsylvania, Philadelphia	824	Pan-Ig	4 910 139	90
Minnesota, Minneapolis	860	Pan-Ig	3 857 479	90
USA (California, Bay Area)[24]	1 000	IgG	7 753 000	90
USA (California, Los Angeles)[22]	863	IgG and IgM	7 892 000	92
USA (California, San Francisco)[33]	3 953	IgG (also PCR testing)	5174 (in census tract 022 901)	95
USA (California, Santa Clara)[19]	3 300	IgG and IgM	1 928 000	90
USA (Idaho, Boise)[9]	4 856	IgG	481 587 (Ada county)	92
USA (Georgia, DeKalb and Fulton counties)[53]	696	Total Ig	1 806 672	88 (Georgia)
USA (Idaho, Blaine county)[46]	917	IgG	23 089	92
USA (Indiana)[54]	3 629	IgG (also RT–PCR done)	6 730 000	89
USA (Louisiana, Baton Rouge)[63]	138	IgG	699 200 (East Baton Rouge, West Baton Rouge, Ascension, Livingston)	92 (Louisiana)
USA (Louisiana, Orleans and Jefferson Parish)[37]	2 640	IgG	825 057	92 (Louisiana)
USA (New York)[23]	15 101	IgG	19 450 000	90
USA, New York[56]				
Columbia University Medical Center, New York City	742 (2–30 March)	IgG and IgM	9 260 870	89
CareMount central laboratory, five New York state counties	1 841	IgG and IgM	10 189 130 (New York state excluding New York City)	89
USA (New York, Brooklyn)[27]	11 092	IgG	2 559 903	91
USA (Rhode Island), blood donors[45]	1 996	IgG and IgM	1 059 000	88

COVID-19: coronavirus disease-19; Ig: immunoglobin; RT–PCR: real-time polymerase chain reaction.

[a] Dates in brackets are the specific dates used when seroprevalence was evaluated at multiple consecutive time points or setting.

[b] Some studies focused on age-restricted populations of the specific location under study, for example: people 17–70 years in the Denmark blood donor study (*n* = 3 800 000); people 18–79-years in the Luxembourg study (*n* = 483 000);

people < 70 years in the Netherlands blood donor study (*n* = 13 745 768); people ≥ 18 years in the New York state study (*n* = 15 280 000); people > 19 years in the Utah population of the 10-state United States study (*n* = 2 173 082); people ≥ 18 years in Blaine county, Idaho (*n* = 17 611); people 15–64 years in the Kenya blood donor study (*n* = 27 150 165); people > 14 years living in private premises in Hungary; people > 18 years (*n* = 551 185) in Baton Rouge, Louisiana; people 18–65 years working in urban locations in Pakistan (*n* = 22 100 000); and people > 18 years in Srinagar District, India (*n* = 1 020 000). In this table and subsequent analyses, the entire population in the location is considered for consistency across studies.

[c] Information in parenthesis specify the population.

[d] Participants were recruited from a large number of districts, but most districts had very few participants; here I included the population of the nine districts with > 1:10 000 sampling ratio (846/1000 participants came from these nine districts).

[e] Considered positive if both IgG and IgA were positive; in the other studies, detection of any antibody was considered positive.

Table 3. **Prevalence of COVID-19 and estimated number of people infected, 2020**

Country (location)	**Seroprevalence (%)**		**Estimated no. of people infected**
	Crude	**Adjusted (adjustments)**	
Argentina (Barrio Padre Mugica)[47]	ND	53.4 (age, sex, household, non-response)	26 691
Belgium[38]	5.7	6.0 (sampling, age, sex, province)	695 377
Brazil (133 cities)[25]	1.39	1.62 overall, varying from 0 to 25.0 across 133 cities (test, design)	1 209 435[a]
Brazil (Espirito Santo)[34]	2.1	ND	84 391
Brazil (Maranhao)[68]	37	40.4 (clustering, stratification, non-response)	2 877 454
Brazil (Rio de Janeiro), blood donors[41]	6	4.7 (age, sex, test)	811 452
Brazil (Rio Grande do Sul)[17]	0.222	0.222 (sampling)[b]	25 283
Brazil (Sao Paulo)[42]	5.2	4.7 (sampling design)	14 017
Canada (British Columbia)[50]	0.45	0.55 (age)	27 890
Chile (Vitacura)[43]	11.2	ND	9 500
China, blood donors[55]			
Wuhan	3.87	ND	433 827
Shenzhen	0.06	ND	7 818
Shijiazhuang	0.02	ND	2 206
China (Wuhan)[14]	10	ND	1 108 000
China (Wuhan)[32]	8.36 (3.53 for entire period)	ND (2.80 (age, sex, test) for entire period)	926 288
China (Guangzhou), blood donors[60]	0.09	ND	104 783
China (several regions)[40]			
Hubei (not Wuhan)	3.6	ND	1 718 110
Chongqing	3.8	ND	11 956 109
Sichuan	0.6	ND	487 847
Guangdong	2.2	ND	2 522 010
Croatia[26]	1.27[c]	ND	51 765
Denmark, blood donors[12]	2	1.9 (test)	109 665
Denmark (Faroe Islands)[52]	0.6	0.7 (test)	365
France (Crepy-en-Valois)[39]	10.4	ND	620 105
France (Oise)[13]	25.9	ND	1 548 000
Germany (Gangelt)[16]	15	20.0 (test, cluster, symptoms)	2 519
Germany (Frankfurt)[21]	0.6	ND	16 086
Greece[62]	0.42 (April)	0.49 (age, sex, region)[d]	51 023
Hungary[57]	0.67	0.68 (design, age, sex, district)	65 671
Iceland[58]	2.3 (quarantined), 0.3 (unknown exposure)	0.9 (including those positive by PCR)	3 177
India (Mumbai)[61]	54.1 in slum areas, 16.1 in non-slum areas	58.4 in slum areas, 17.3 in non-slum areas (test, age, sex)	534 750
India (Srinagar)[67]	3.8	3.6 (age, sex)	54 000
Islamic Republic of Iran (Guilan)[8]	22	33.0 (test, sampling)	770 000
Italy (Apulia), blood donors[31]	0.99	ND	39 887
Japan (Kobe)[11]	3.3	2.7 (age, sex)	40 999
Japan (Tokyo)[29]	3.83	ND	532 450
Japan (Utsunomiya City)[48]	0.4	1.23 (age, sex, distance to clinic, district, cohabitants)	6 378
Kenya, blood donors[44]	5.6	5.2 (age, sex, region, test)	2 783 453
Luxembourg[20]	1.9	2.1 (age, sex, district)	12 684
Netherlands, blood donors[15]	2.7	ND	461 622
Netherlands (Rotterdam)[64]	3	ND	512 910

Pakistan (Karachi)[49]	16.3 (20.0 in East, 12.7 in Malir)	11.9 (age, sex; 15.1 in East, 8.7 in Malir)	1 987 300
Pakistan (urban)[66]	17.5	ND	13 825 000
Qatar[51]	30.4 (24.0 for entire period)	ND	851 200
Republic of Korea[59]	0.07	ND	1 867
Spain[36]	ND	5.0[e] (sampling, age, sex, income)	2 347 000
Spain (Barcelona)[30]	14.3	ND	1 081 938
Switzerland (Geneva)[10]	10.6	10.9 (test, age, sex)	54 500
Switzerland (Zurich)[28]	Unclear	1.3 in patients during 1–15 April and 1.6 in blood donors in May (multivariate Gaussian conditioning)	19 773 (Zurich); 30 888 (Zurich and Lucerne)
United Kingdom (England)[65]	5.6	6.0 (test, sampling)	3 360 000
United Kingdom (Scotland) blood donors[18]	1.2	ND	64 800
USA (six states)[35]		(age, sex, test)	
Washington, Puget Sound	1.3	1.1	48 291
Utah	2.4	2.2	71 550
New York, New York City	5.7	6.9	641 778
Missouri	2.9	2.7	161 936
Florida, south	2.2	1.9	117 389
Connecticut	4.9	4.9	176 012
Louisiana	ND	5.8	267 033
California, San Francisco Bay	ND	1	64 626
Pennsylvania, Philadelphia	ND	3.2	156 633
Minnesota, Minneapolis	ND	2.4	90 651
USA (California, Bay Area)[24]	0.4 (blood donors)	0.1 (test and confirmation)	7 753
USA (California, Los Angeles)[22]	4.06	4.65 (test, sex, race and ethnicity, income)	367 000
USA (California, San Francisco)[33]	4.3 in the census track	6.1 (age, sex, race and ethnicity, test)	316
USA (California, Santa Clara)[19]	1.5	2.6 (test, sampling, cluster)	51 000
USA (Idaho, Boise)[9]	1.79	ND	8620
USA (Georgia, DeKalb and Fulton counties)[53]	2.7	2.5 (age, sex, race and ethnicity)	45 167
USA (Idaho, Blaine county)[46]	22.4	23.4 (test, age, sex, household)	5 403
USA (Indiana)[54]	2.3 (IgG or PCR)	2.8 (age, race, Hispanic ethnicity)	187 802
USA (Louisiana, Baton Rouge)[63]	6	6.6 (census, race, parish) including PCR positives	46 147
USA (Louisiana, Orleans and Jefferson Parish)[37]	6.9 (IgG or PCR)	6.9 for IgG (census weighting, demographics)	56 578
USA (New York)[23]	12.5	14.0 (test, sex, age race and ethnicity, region)	2 723 000
USA, New York[56]			
Columbia University Medical Center, New York City	5	ND	463 044
CareMount central laboratory, five New York state counties	1.8	ND	183 404
USA (New York, Brooklyn)[27]	47	ND	1 203 154
USA (Rhode Island), blood donors[45]	3.9	ND	41 384

COVID-19: coronavirus disease 2019; ND: no data available; PCR: polymerase chain reaction; test: test performance.

[a] The authors calculated 760 000 to be infected in the 90 cities that had 200–250 samples tested, but many of the other 43 cities with < 200 samples may be equally or ever better represented since they tended to be smaller than the 90 cities (mean population 356 213 versus 659 326).

[b] An estimate is also provided adjusting for test performance, but the assumed specificity of 99.0% seems inappropriately low, since as part of the validation process the authors found that several of the test-positive individuals had household members who were also infected, thus the estimated specificity was deemed by the authors to be at least 99.95%.

[c] 1.20% in workers in Split without mobility restrictions, 3.37% in workers in Knin without mobility restrictions, 1.57% for all workers without mobility restrictions; Split and Knin tended to have somewhat higher death rates than nationwide Croatia, but residence of workers is not given, so the entire population of the country is used in the calculations.

[d] An estimate is also provided adjusting for test performance resulting in adjusted seroprevalence of 0.23%, but this seems inappropriately low, since the authors report that all positive results were further validated by ELISA.

[e] 5.0% with point of care test, 4.6% with immunoassay, 3.7% with both tests positive, 6.2% with at least one test positive.

Notes: Of the studies where seroprevalence was evaluated at multiple consecutive time points, the seroprevalence estimate was the highest in the most recent time interval with few exceptions, for example: in the Switzerland (Geneva) study,[10] the highest value was seen 2 weeks before the last time interval; in the Switzerland (Zurich) study,[28] the highest value was seen in the period 1–15 April for patients at the university hospital and in May for blood donors; and in the China (Wuhan) study,[32] the highest value was seen about 3 weeks before the last time interval.

Table 4. **Deaths from COVID-19 and inferred infection fatality rates, overall and in people younger than 70 years, by location, 2020**

Location	Deaths from COVID-19, no. (date)	Inferred infection fatality rate (corrected), %	% of deaths from COVID-19 in people < 70 years[a]	Infection fatality rate in people < 70 years (corrected), %
Argentina (Barrio Padre Mugica)[47]	44 (1 July)	0.16 (0.13)	~70	0.11 (0.09)
Belgium[38]	7594 (30 April)	1.09 (0.87)	10	0.13 (0.10)
Brazil (133 cities)[25]	–[b]	Median 0.30 (0.27)	31 (< 60 years)	0.10 (0.9)
Brazil (Espirito Santo)[34]	363 (21 May)	0.43 (0.39)	31 (Brazil, < 60 years)	0.14 (0.13)
Brazil (Maranhao)[68]	4272 (8 August)	0.15 (0.14)	23	0.04 (0.03)
Brazil (Rio de Janeiro), blood donors[41]	1019 (3 May)	0.12 (0.11)	31 (Brazil, < 60 years)	0.04 (0.04)
Brazil (Rio Grande do Sul)[17]	124 (14 May)	0.49 (0.39)	31 (Brazil, < 60 years)	0.19 (0.15)
Brazil (Sao Paulo)[c,42]	Unknown (15 May)	Unknown, but likely > 0.4	31 (Brazil, < 60 years)	Unknown, but likely > 0.1
Canada (British Columbia)[50]	164 (28 May)	0.59 (0.59)	13	0.08 (0.08)
Chile (Vitacura) [c,43]	Unknown (18 May)	Unknown, but likely < 0.2	36 (Chile)	Unknown, but likely < 0.1
China, blood donors[55]				
Wuhan	1935 (20 February)	0.45 (0.41)	50	0.24 (0.22)
Shenzhen	1 (5 March)	0.01 (0.01)	About 50 (if similar to Wuhan)	0.01 (0.01)
Shijiazhuang	1 (27 February)	0.05 (0.04)	About 50 (if similar to Wuhan)	0.03 (0.02)
China (Wuhan)[14]	3869 (2 May)	0.35 (0.31)	50	0.19 (0.15)
China (Wuhan)[32]	3869 (13 April)	0.42 (0.38)	50	0.23 (0.21)
China (Guangzhou), blood donors[60]	8 (5 April)	0.00 (0.00)	About 50 (if similar to Wuhan)	0.00 (0.00)
China (several regions)[40]				
Hubei (not Wuhan)	643 (12 April)	0.04 (0.03)	About 50 (if similar to Wuhan)	0.02 (0.02)
Chongqing	6 (12 April)	0.00 (0.00)	About 50 (if similar to Wuhan)	0.00 (0.00)
Guangdong	8 (12 April)	0.00 (0.00)	About 50 (if similar to Wuhan)	0.00 (0.00)
Sichuan	3 (12 April)	0.00 (0.00)	About 50 (if similar to Wuhan)	0.00 (0.00)
Croatia[26]	79 (3 May)	0.15 (0.14)	13	0.02 (0.02)
Denmark, blood donors[12]	370 (21 April)	0.34 (0.27)	12	0.05 (0.04)
Faroe Islands[52]	0 (5 May)	0.00 (0.00)	0	0.00 (0.00)
France (Crepy-en-Valois)[39]	2325 (5 May)[d]	0.37 (0.30)	7 (France, < 65 years)	0.04 (0.03)
France (Oise)[13]	932 (7 April)[d]	0.06 (0.05)	7 (France, < 65 years)	0.01 (0.01)
Germany (Gangelt)[16]	7 (15 April)	0.28 (0.25)	0	0.00 (0.00)
Germany (Frankfurt)[21]	42[e] (17 April)	0.26 (0.21)	14 (Germany)	0.04 (0.03)
Greece[62]	121 (22 April)	0.24 (0.19)	30	0.09 (0.07)
Hungary[57]	442 (15 May)	0.67 (0.54)	No data	No data
Iceland[58]	10 (1 June)	0.30 (0.30)	30	0.10 (0.10)
India (Mumbai)[61]	495 (13–20 July)	0.09 (0.07)	50 (< 60 years, India)	0.04 (0.03)
India (Srinagar)[67]	35 (15 July)[f]	0.06 (0.05)	50 (< 60 years, India)	0.03 (0.03)
Islamic Republic of Iran (Guilan)[8]	617 (23 April)	0.08 (0.07)	No data	No data
Italy (Apulia), blood donors[31]	530 (22 May)	1.33 (1.20)	15 (Italy)	0.24 (0.22)
Japan (Kobe)[11]	10 (mid-April)	0.02 (0.02)	21 (Japan)	0.01 (0.01)
Japan (Tokyo)[29]	189 (11 May)	0.04 (0.03)	21 (Japan)	0.01 (0.01)
Japan (Utsunomiya City)[48]	0 (14 June)	0.00 (0.00)	0	0.00 (0.00)

Kenya, blood donors[44]	64 (31 May)	0.00 (0.00)	58 (< 60 years)	0.00 (0.00)
Luxembourg[20]	92 (2 May)	0.73 (0.58)	9	0.07 (0.06)
Netherlands, blood donors[15]	3134 (15 April)	0.68 (0.68)	11	0.09 (0.09)
Netherlands (Rotterdam)[64]	3134 (15 April)	0.65 (0.52)	11	0.08 (0.06)
Pakistan (Karachi)[49]	~1500 (9 July)[g]	0.08 (0.07)	~70	0.06 (0.05)
Pakistan (urban)[66]	5266 (13 July)[h]	0.04 (0.04)	~70	0.03 (0.03)
Qatar[51]	93 (19 June)	0.01 (0.01)	74	0.01 (0.01)
Republic of Korea[59]	2 (3 June)[i]	0.10 (0.09)	0	0.00 (0.00)
Spain[36]	26 920 (11 May)	1.15 (0.92)	13	0.18 (0.14)
Spain (Barcelona)[30]	5137 (2 May)	0.48 (0.48)	13 (Spain)	0.07 (0.07)
Switzerland (Geneva)[10]	243 (30 April)	0.45 (0.36)	8	0.04 (0.03)
Switzerland (Zurich)[28]	107 (15 April, Zurich), 147 (22 May, Zurich and Lucerne)	0.51 (0.41)	8 (Switzerland)	0.05 (0.04)
England[65]	38 854 (9 July)	1.16 (0.93)	20	0.27 (0.22)
Scotland, blood donors[18]	47 (1 April)	0.07 (0.06)	9 (< 65 years)	0.01 (0.01)
USA (10 states)[35]				
Washington, Puget Sound	207 (4 April)	0.43 (0.43)	10 (state, < 60 years)	0.05 (0.05)
Utah	58 (4 May)	0.08 (0.08)	28 (< 65 years)	0.03 (0.03)
New York	4146 (4 April)	0.65 (0.65)	34 (state)	0.25 (0.25)
Missouri	329 (30 April)	0.20 (0.20)	23	0.05 (0.05)
Florida, south	295 (15 April)	0.25 (0.25)	28 (state)	0.08 (0.08)
Connecticut	2718 (6 May)	1.54 (1.54)	18	0.31 (0.31)
Louisiana	806 (11 April)	0.30 (0.30)	32	0.10 (0.10)
California, San Francisco Bay	321 (1 May)	0.50 (0.50)	25	0.14 (0.14)
Pennsylvania, Philadelphia	697 (26 April)	0.45 (0.45)	21 (state)	0.10 (0.10)
Minnesota, Minneapolis	436 (13 May)	0.48 (0.48)	20 (state)	0.10 (0.10)
USA (California, Bay Area)[24]	12 (22 March)	0.15 (0.12)	25	0.04 (0.03)
USA (California, Los Angeles)[22]	724 (19 April)	0.20 (0.18)	24 (< 65 years)	0.06 (0.05)
USA (California, San Francisco)[33]	0 (4 May)	0.00 (0.00)	0	0.00 (0.00)
USA (California; Santa Clara)[19]	94 (22 April)	0.18 (0.17)	35	0.07 (0.06)
USA (Idaho, Boise)[9]	14 (24 April)	0.16 (0.13)	14 (Idaho)	0.02 (0.02)
USA (Georgia)[53]	198 (7 May)	0.44 (0.44)	30	0.15 (0.15)
USA (Idaho, Blaine county)[46]	5 (19 May)	0.10 (0.08)	14 (Idaho)	0.02 (0.01)
USA (Indiana)[54]	1099 (30 April)	0.58 (0.46)	24	0.16 (0.13)
USA (Louisiana, Baton Rouge)[63]	420 (30 July)	0.91 (0.73)	32 (Louisiana)	0.32 (0.25)
USA (Louisiana, Orleans and Jefferson Parish)[37]	925 (16 May)	1.63 (1.31)	32	0.57 (0.46)
USA (New York)[23]	18 610 (30 April)[j]	0.68 (0.54)[j]	34	0.26 (0.23)[d]
USA (New York Columbia University Medical Center, New York City and CareMount central laboratory, five New York state counties)[56]	965 (28 March, New York state)	0.15 (0.14)	34	0.06 (0.05)
USA (New York, Brooklyn)[27]	4894 (19 May)[j]	0.41 (0.33)[j]	34 (New York state)	0.15 (0.14)[d]
USA (Rhode Island), blood donors[45]	430 (11 May)	1.04 (0.83)	17	0.20 (0.16)

COVID-19: coronavirus disease 2019.

[a] Whenever the number or proportion of COVID-19 deaths at age < 70 years was not provided in the paper, I retrieved the proportion of these deaths from situation reports of the relevant location. If I could not find this information for the specific location, I used a larger geographic area. For Brazil, the closest information that I found was from a news report.[77] For Croatia, I retrieved data on age for 45/103 deaths through Wikipedia.[78]

[b] Data are provided by the authors for deaths per 100 000 population in each city along with inferred infection fatality rate in each city, with wide differences across cities; the infection fatality rate shown here is the median across the 36 cities with 200–250 samples and at least one positive sample (the interquartile range for the uncorrected infection fatality rate is 0.20–0.60% and across all cities is 0–2.4%, but with very wide uncertainty in each city). A higher infection fatality rate is alluded to in the preprint, but the preprint also shows a scatter diagram for survey-based seroprevalence versus reported deaths per population with a regression slope that agrees with an infection fatality rate of 0.3%.

[c] Information on deaths was not available for the specific locations. In the Sao Paulo study, the authors selected six districts of Sao Paulo most affected by COVID-19, they do not name the districts and the number of deaths as of mid-May is not available, but using data for death rates across all Sao Paulo would give an infection fatality rate of > 0.4% overall. In the Vitacura study, similarly one can infer from the wider Santiago metropolitan area that the infection fatality rate in the Vitacura area would probably be < 0.2% overall.

[d] For France, government situation reports provide the number of deaths per region only for in-hospital deaths; therefore, I multiplied the number of in-hospital deaths by a factor equal to: total number of deaths/in-hospital deaths for all of France.

[e] Estimated from no. of deaths in Hesse province on 17 April × proportion of deaths in the nine districts with key enrolment (enrolment ratio > 1:10 000) in the study among all deaths in Hesse province.

[f] I calculated the approximate number of deaths assuming the same case fatality ratio in the Srinagar district as in the Jammu and Kashmir state where it is located.

[g] For Karachi, it is assumed that about 30% of COVID-19 deaths in Pakistan are in Karachi (since about 30% of the cases are there).

[h] The number of deaths across all Pakistan; I assumed that this number is a good approximation of deaths in urban areas (most deaths occur in urban areas and there is some potential underreporting).

[i] I calculated the approximate number of deaths from the number of cases in the study areas in south-western Seoul, assuming a similar case fatality as in Seoul overall.

[j] Confirmed COVID-19 deaths; inclusion of probable COVID-19 deaths would increase the infection fatality rate estimates by about a quarter.

Table 5. **Infection fatality rates for coronavirus disease-19 inferred from preliminary nationwide seroprevalence data, 2020**

Country	**Sample size (antibody)**	**Date**	**Reported seroprevalence (%)**	**Population, no.**	**Deaths, no. (date)**	**Inferred infection fatality rate (corrected), %**
Afghanistan[75]	9 500 (IgG?)	August?	31.5	39 021 453	1300 (8 May)	0.01 (0.01)
Czechia[71]	26 549 (IgG)	23 April–1 May	0.4	10 710 000	252 (4 May)	0.59 (0.47)
Finland[69]	674 (IgG)	20–26 April[a]	2.52	5 541 000	211 (30 April)	0.15 (0.12)
Georgia[76]	1 068 (IgG?)	18–27 May	1	3 988 264	12 (30 May)	0.03 (0.03)[b]
Israel[72]	1 709 (IgG?)	May	2–3	9 198 000	299 (10 June)	0.13 (0.10)[c]
Russian Federation[74]	650 000 (IgG?)	June?	14	145 941 776	5859 (7 June)	0.03 (0.03)
Slovenia[73]	1368 (IgG?)	April	3.1	2 079 000	92 (1 May)	0.14 (0.11)
Sweden[70]	1 200 (IgG)	18–24 May	6.3	10 101 000	4501 (28 May)	0.71 (0.57)

COVID-19: coronavirus disease 2019; Ig: immunoglobin.

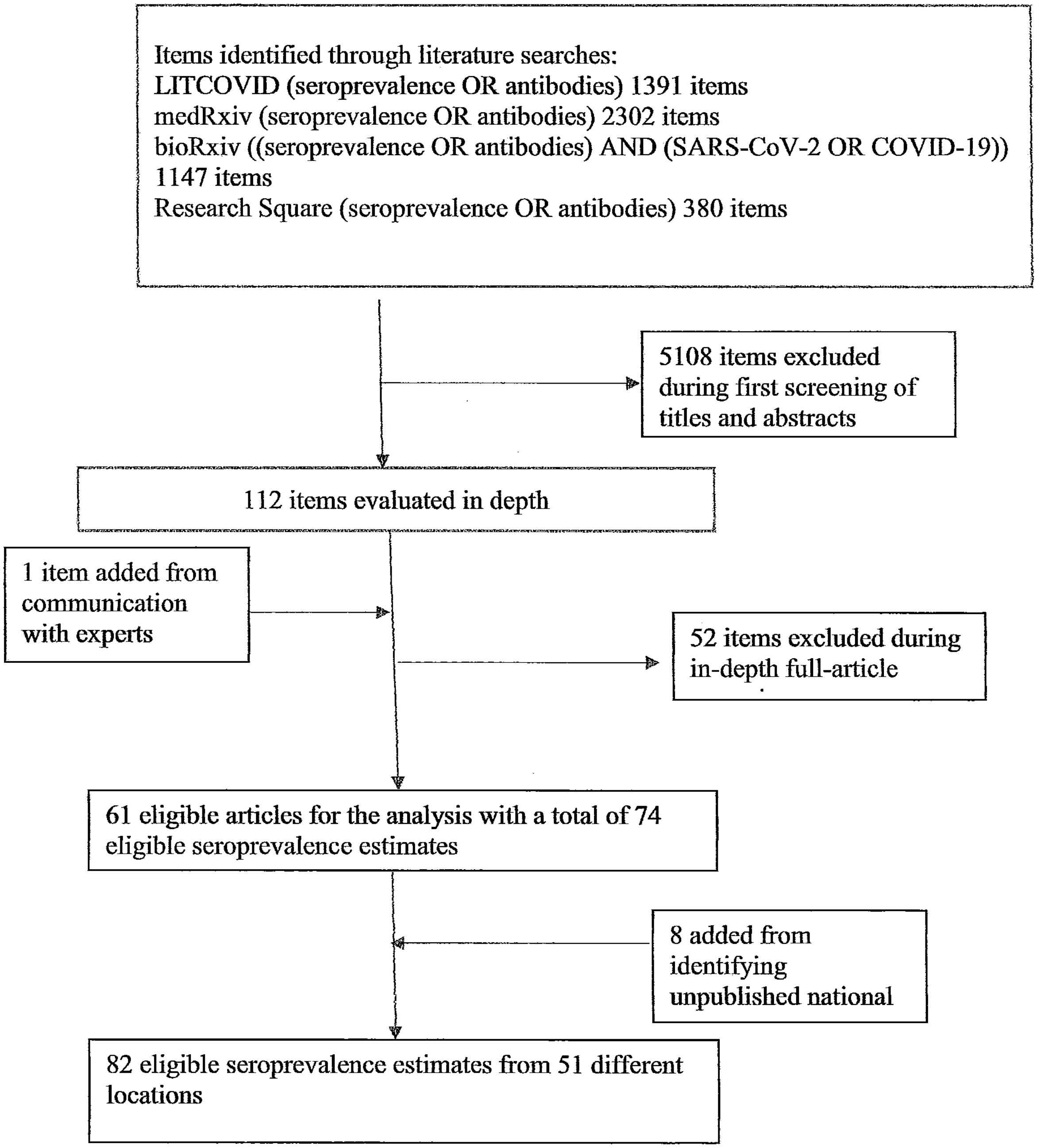
[a] The seroprevalence was slightly lower in subsequent weeks.

[b] The survey was done in Tbilisi, the capital city with a population 1.1 million. I could not retrieve the count of deaths in Tbilisi, but if more deaths happened in Tbilisi, then the infection fatality rate may be higher, but still < 0.1%.

[c] Assuming a seroprevalence of 2.5%.

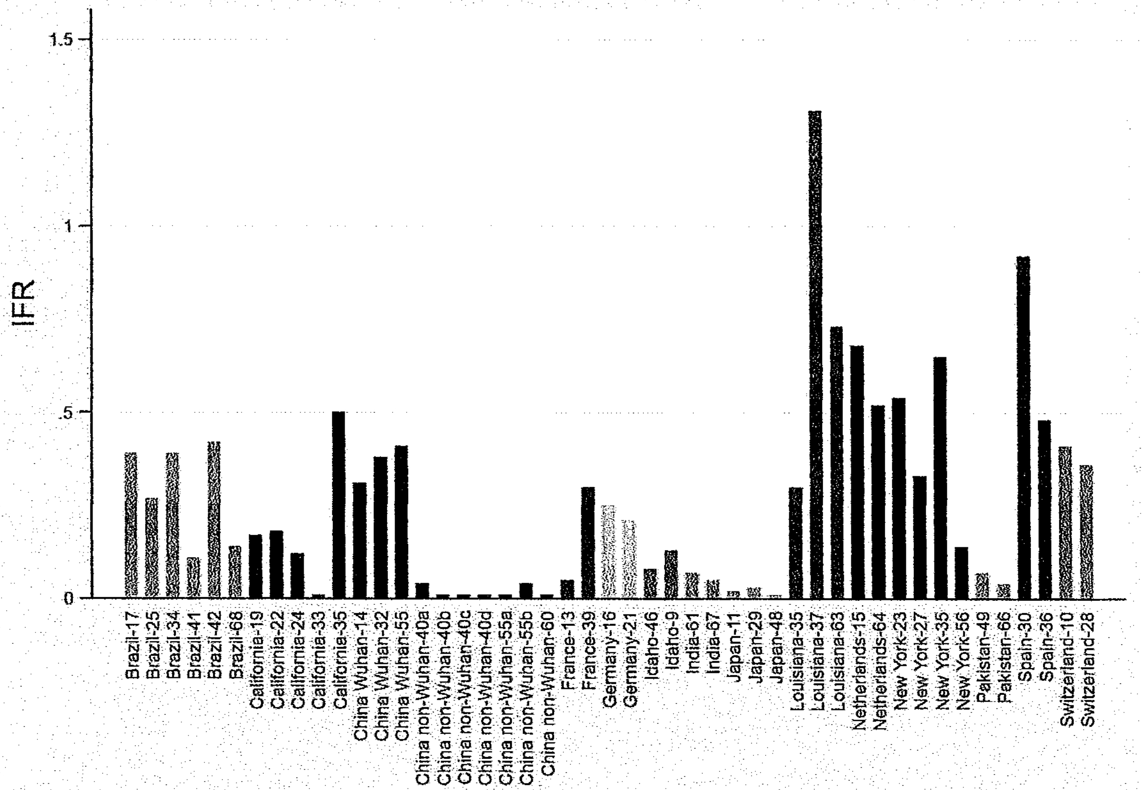
Notes: These are countries for which no eligible studies were retrieved in the literature search. The results of these studies have been announced to the press and/or in preliminary reports, but are not yet peer reviewed and published. The question marks indicate that the antibody type or date were not clear.

Fig. 1. **Flowchart for selection of seroprevalence studies on severe acute respiratory syndrome coronavirus 2, 2020**


Items identified through literature searches:
LITCOVID (seroprevalence OR antibodies) 1391 items
medRxiv (seroprevalence OR antibodies) 2302 items
bioRxiv ((seroprevalence OR antibodies) AND (SARS-CoV-2 OR COVID-19)) 1147 items
Research Square (seroprevalence OR antibodies) 380 items
5108 items excluded during first screening of titles and abstracts
112 items evaluated in depth
1 item added from communication with experts
52 items excluded during in-depth full-article
61 eligible articles for the analysis with a total of 74 eligible seroprevalence estimates
8 added from identifying unpublished national
82 eligible seroprevalence estimates from 51 different locations

COVID-19: coronavirus disease 2019; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

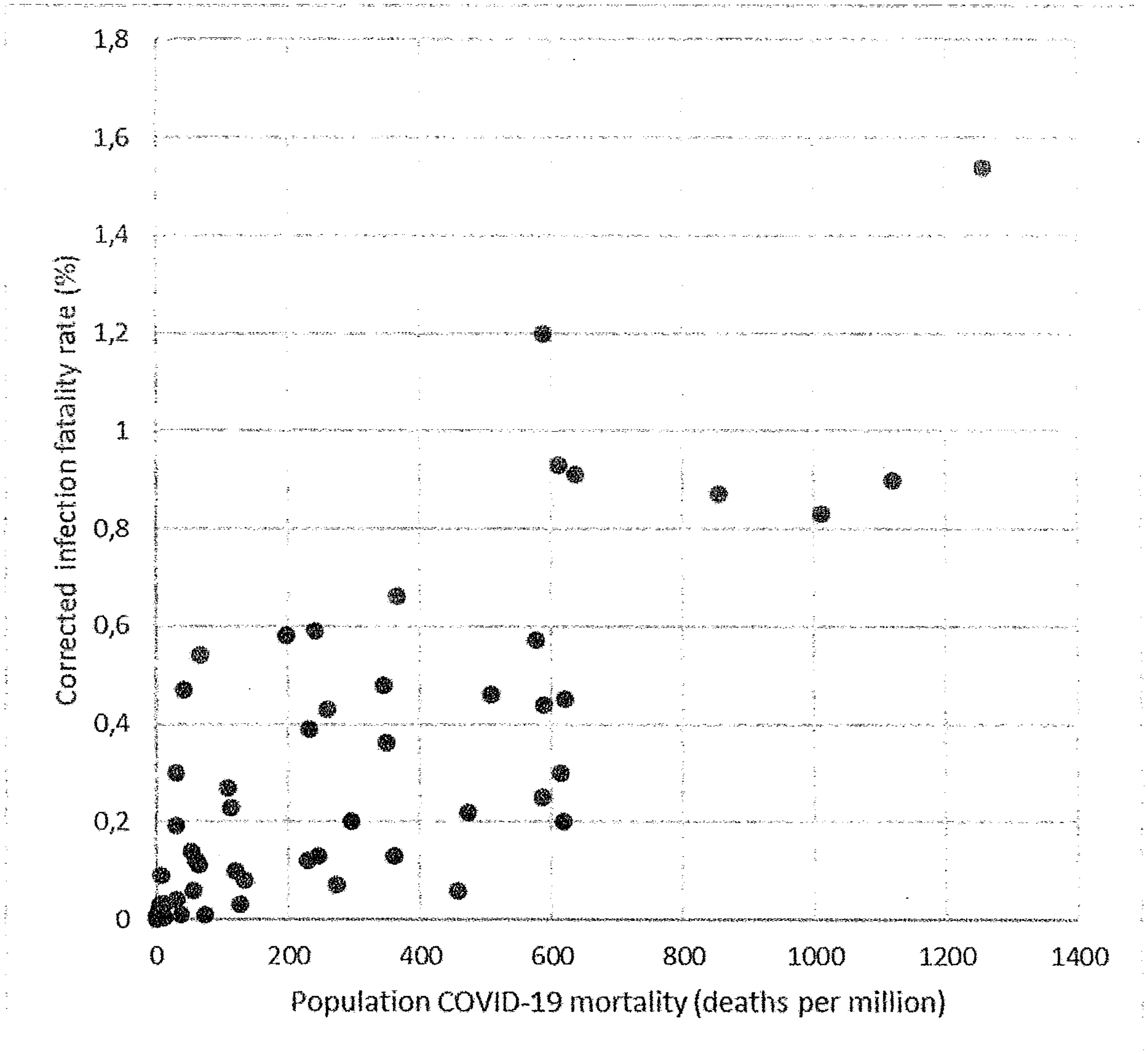
Fig. 2. **Estimates of infection fatality rates for COVID-19 in locations that had two or more estimates, 2020**



COVID-19: coronavirus disease 2019.

Notes: Locations are defined at the level of countries, except for the USA where they are defined at the level of states and China is separated into Wuhan and non-Wuhan areas. Corrected infection fatality rate estimates are shown (correcting for what types of antibodies were assayed).

Fig. 3. **Corrected estimates of COVID-19 infection fatality rate in each location plotted against COVID-19 mortality rate as of September 12, 2020 in that location**



COVID-19: coronavirus disease 2019

Notes: Locations are defined at the level of countries, except for the United Kingdom of Great Britain and Northern Ireland where they are defined by jurisdiction, USA are defined at the level of states and China is separated into Wuhan and non-Wuhan areas. Included locations are: Afghanistan; Argentina, Belgium Brazil; Canada; Chile; China (non-Wuhan and Wuhan); Croatia; Czechia; Denmark; Faroe Islands; Finland; France; Georgia; Germany; Greece; Hungary; Iceland; India; Islamic Republic of Iran (Islamic Republic of); Israel; Italy; Japan; Kenya; Luxembourg; Netherlands; Pakistan; Qatar; Russian Federation; Slovenia; Republic of Korea; Spain; Sweden; Switzerland; United Kingdom (England, Scotland); and USA (California, Connecticut, Florida, Georgia, Idaho, Indiana, Louisiana, Minnesota, Missouri, New York, Pennsylvania, Rhode Island, Utah, Washington). When several infection fatality rate estimates were available from multiple studies for a location, the sample size-weighted mean is used. One outlier location with very high deaths per million population (1702 for New York) is not shown.

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CORMAN-
DROSTEN
REVIEW
REPORT

HOME MAIN REVIEW REPORT ADDENDUM
RETRACTION LETTER EUROSURVEILLANCE RESPONSE
CONSORTIUM FALSE-POSITIVES ARTICLES PODCASTS
OUTREACH DOWNLOADS IMPRINT MIRRORS

CURATED BY AN
INTERNATIONAL
CONSORTIUM OF SCIENTISTS
IN LIFE SCIENCES (ICSLS)

Review report Corman-Drosten et al. Eurosurveillance 2020

November 27, 2020

This extensive review report has been officially submitted to Eurosurveillance editorial board on 27th November 2020 via their submission-portal, enclosed to this review report is a retraction request letter, signed by all the main & co-authors. First and last listed names are the first and second main authors. All names in between are co-authors.

External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results.

Pieter Borger(1), Bobby Rajesh Malhotra(2) , Michael Yeadon(3) , Clare Craig(4), Kevin McKernan(5) , Klaus Steger(6) , Paul McSheehy(7) , Lidiya Angelova(8), Fabio Franchi(9), Thomas Binder(10), Henrik Ullrich(11) , Makoto Ohashi(12), Stefano Scoglio(13), Marjolein Doesburg-van Kleffens(14), Dorothea Gilbert(15), Rainer Klement(16), Ruth Schruefer(17), Berber W. Pieksma(18), Jan Bonte(19), Bruno H. Dalle Carbonare(20), Kevin P. Corbett(21), Ulrike Kämmerer(22)

ABSTRACT

In the publication entitled "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR" (Eurosurveillance 25(8) 2020) the authors present a diagnostic workflow and RT-qPCR protocol for detection and diagnostics of 2019-nCoV (now known as SARS-CoV-2), which they claim to be validated, as well as being a robust diagnostic methodology for use in public-health laboratory settings.

In light of all the consequences resulting from this very publication for societies worldwide, a group of independent researchers performed a point-by-point review of the aforesaid publication in which 1) all components of the presented test design were cross checked, 2) the RT-qPCR protocol-recommendations were assessed w.r.t. good laboratory practice, and 3) parameters examined against relevant scientific literature covering the field.

The published RT-qPCR protocol for detection and diagnostics of 2019-nCoV and the manuscript suffer from numerous technical and scientific errors, including insufficient primer design, a problematic and insufficient RT-qPCR protocol, and the absence of an accurate test validation. Neither the presented test nor the manuscript itself fulfils the requirements for an acceptable scientific publication. Further, serious conflicts of interest of the authors are not mentioned. Finally, the very short timescale between submission and acceptance of the publication (24 hours) signifies that a systematic peer review process was either not performed here, or of problematic poor quality. We provide compelling evidence of several scientific inadequacies, errors and flaws.

Considering the scientific and methodological blemishes presented here, we are confident that the editorial board of Eurosurveillance has no other choice but to retract the publication.

CONCISE REVIEW REPORT

This paper will show numerous serious flaws in the Corman-Drosten paper, the significance of which has led to worldwide misdiagnosis of infections attributed to SARS-CoV-2 and associated with the disease COVID-19. We are confronted with stringent lockdowns which have destroyed many people's lives and livelihoods, limited access to education and these imposed restrictions by governments around the world are a direct attack on people's basic rights and their personal freedoms, resulting in collateral damage for entire economies on a global scale.

There are ten fatal problems with the Corman-Drosten paper which we will outline and explain in greater detail in the following sections.

The first and major issue is that the novel Coronavirus SARS-CoV-2 (in the publication named 2019-nCoV and in February 2020 named SARS-CoV-2 by an international consortium of virus experts) is based on in silico (theoretical) sequences, supplied by a laboratory in China [1], because at the time neither control material of infectious ("live") or inactivated SARS-CoV-2 nor isolated genomic RNA of the virus was available to the authors. To date no validation has been performed by the authorship based on isolated SARS-CoV-2 viruses or full length RNA thereof. According to Corman et al.:

> ***"We aimed to develop and deploy robust diagnostic methodology for use in public health laboratory settings without having virus material available." [1]***

The focus here should be placed upon the two stated aims: a) *development* and b) *deployment of a diagnostic test for use in public health laboratory settings.* These aims are not achievable without having any actual virus material available (e.g. for determining the infectious viral load). In any case, only a protocol with maximal accuracy can be the mandatory and primary goal in any scenario-outcome of this magnitude. Critical viral load determination is mandatory information, and it is in Christian Drosten's group responsibility to perform these experiments and provide the crucial data.

Nevertheless these in silico sequences were used to develop a RT-PCR test methodology to identify the aforesaid virus. This model was based on the assumption that the novel virus is very similar to SARS-CoV from 2003 as both are beta-coronaviruses.

The PCR test was therefore designed using the genomic sequence of SARS-CoV as a control material for the Sarbeco component; we know this from our personal email-communication with [2] one of the co-authors of the Corman-Drosten paper. This method to model SARS-CoV-2 was described in the Corman-Drosten paper as follows:

> ***"the establishment and validation of a diagnostic workflow for 2019-nCoV screening and specific confirmation, designed in absence of available virus isolates or original patient specimens. Design and validation were enabled by the close genetic relatedness to the 2003 SARS-CoV, and aided by the use of synthetic nucleic acid technology."***

The Reverse Transcription-Polymerase Chain Reaction (RT-PCR) is an important biomolecular technology to rapidly detect rare RNA fragments, which are known in advance. In the first step, RNA molecules present in the sample are reverse transcribed to yield cDNA. The cDNA is then amplified in the polymerase chain reaction using a specific primer pair and a thermostable DNA polymerase enzyme. The technology is highly sensitive and its detection limit is theoretically 1 molecule of cDNA. The specificity of the PCR is highly influenced by biomolecular design errors.

What is important when designing an RT-PCR Test and the quantitative RT-qPCR test described in the Corman-Drosten publication?

1. The primers and probes:

a) the concentration of primers and probes must be of optimal range
(100-200 nM)
b) must be specific to the target-gene you want to amplify
c) must have an optimal percentage of GC content relative to the total nitrogenous bases
(minimum 40%, maximum 60%)
d) for virus diagnostics at least 3 primer pairs must detect 3 viral genes (preferably as far apart as possible in the viral genome)

2. The temperature at which all reactions take place:

a) DNA melting temperature (>92°)
b) DNA amplification temperature (TaqPol specific)

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> *patient specimens. Design and validation were enabled by the close genetic relatedness to the 2003 SARS-CoV, and aided by the use of synthetic nucleic acid technology."*

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2. The temperature at which all reactions take place:

a) DNA melting temperature (>92°)

b) DNA amplification temperature (TaqPol specific)

c) Tm; the annealing temperature (the temperature at which the primers and probes reach the target binding/detachment, not to exceed 2°C per primer pair). Tm heavily depends on GC content of the primers

3. The number of amplification cycles (less than 35; preferably 25-30 cycles);

In case of virus detection, >35 cycles only detects signals which do not correlate with infectious virus as determined by isolation in cell culture [reviewed in 2]; if someone is tested by PCR as positive when a threshold of 35 cycles or higher is used (as is the case in most laboratories in Europe & the US), the probability that said person is actually infected is less than 3%, the probability that said result is a false positive is 97% [reviewed in 3]

4. Molecular biological validations; amplified PCR products must be validated either by running the products in a gel with a DNA ruler, or by direct DNA sequencing

5. Positive and negative controls should be specified to confirm/refute specific virus detection

6. There should be a Standard Operational Procedure (SOP) available

SOP unequivocally specifies the above parameters, so that all laboratories are able to set up the exact same test conditions. To have a validated universal SOP is essential, because it enables the comparison of data within and between countries.

MINOR CONCERNS WITH THE CORMAN-DROSTEN PAPER

1. In Table 1 of the Corman-Drosten paper, different abbreviations are stated - "nM" is specified, "nm" isn't. Further in regards to correct nomenclature, nm means "nanometer" therefore nm should read nM here.

2. It is the general consensus to write genetic sequences always in the 5'-3' direction, including the reverse primers. It is highly unusual to do alignment with reverse complementary writing of the primer sequence as the authors did in figure 2 of the Corman-Drosten paper. Here, in addition, a wobble base is marked as "y" without description of the bases the Y stands for.

3. Two misleading pitfalls in the Corman-Drosten paper are that their Table 1 does not include Tm-values (annealing-temperature values), neither does it show GC-values (number of G and C in the sequences as %-value of total bases).

MAJOR CONCERNS WITH THE CORMAN-DROSTEN PAPER

A) BACKGROUND

The authors introduce the background for their scientific work as: "The ongoing outbreak of the recently emerged novel coronavirus (2019-nCoV) poses a challenge for public health laboratories as virus isolates are unavailable while there is growing evidence that the outbreak is more widespread than initially thought, and international spread through travelers does already occur".

According to BBC News [4] and Google Statistics [5] there were 6 deaths world-wide on January 21st 2020 - the day when the manuscript was submitted. Why did the authors assume a challenge for public health laboratories while there was no substantial evidence at that time to indicate that the outbreak was more widespread than initially thought?

As an aim the authors declared to develop and deploy robust diagnostic methodology for use in public health laboratory settings without having virus material available. Further, they acknowledge that "The present study demonstrates the enormous response capacity achieved through coordination of academic and public laboratories in national and European research networks."

B) METHODS AND RESULTS

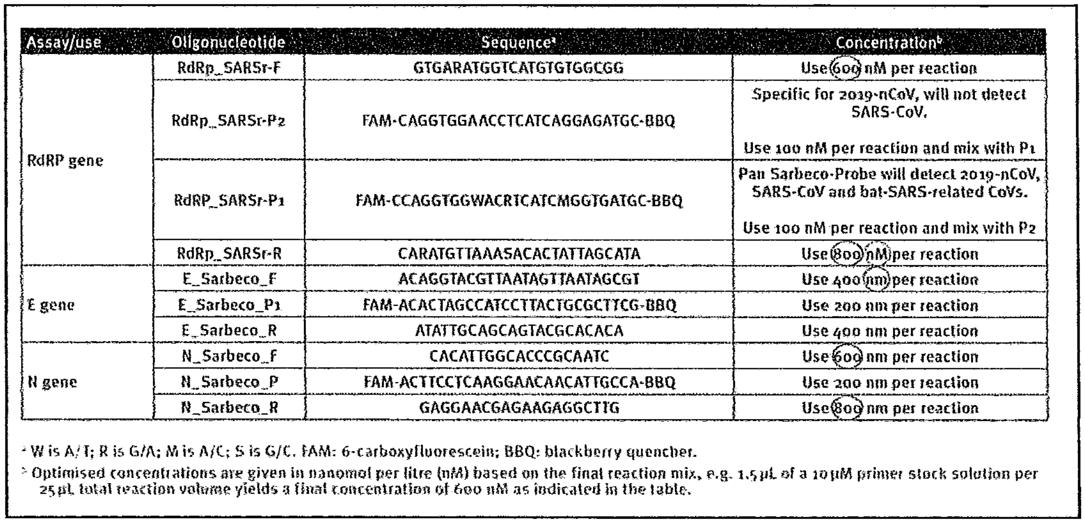
1. Primer & Probe Design

1a) Erroneous primer concentrations

Reliable and accurate PCR-test protocols are normally designed using between 100 nM and 200 nM per primer [7]. In the Corman-Drosten paper, we observe unusually high and varying primer concentrations for several primers (table 1). For the RdRp_SARSr-F and RdRp_SARSr-R primer pairs, 600 nM and 800 nM are described, respectively. Similarly, for the N_Sarbeco_F and N_Sarbeco_R primer set, they advise 600 nM and 800 nM, respectively [1].

It should be clear that these concentrations are far too high to be optimal for specific amplifications of target genes. **There exists no specified reason to use these extremely high concentrations of primers in this protocol. Rather, these concentrations lead to increased unspecific binding and PCR product amplification.**

Table1: Primers and probes (adapted from Corman-Drosten paper; erroneous primer concentrations are highlighted)



Assay/use	Oligonucleotide	Sequence[a]	Concentration[b]
RdRP gene	RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG	Use 600 nM per reaction
	RdRp_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ	Specific for 2019-nCoV, will not detect SARS-CoV. Use 100 nM per reaction and mix with P1
	RdRP_SARSr-P1	FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ	Pan Sarbeco-Probe will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs. Use 100 nM per reaction and mix with P2
	RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA	Use 800 nM per reaction
E gene	E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Use 400 nm per reaction
	E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BBQ	Use 200 nm per reaction
	E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Use 400 nm per reaction
N gene	N_Sarbeco_F	CACATTGGCACCCGCAATC	Use 600 nm per reaction
	N_Sarbeco_P	FAM-ACTTCCTCAAGGAACAACATTGCCA-BBQ	Use 200 nm per reaction
	N_Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Use 800 nm per reaction

[a] W is A/T; R is G/A; M is A/C; S is G/C. FAM: 6-carboxyfluorescein; BBQ: blackberry quencher.

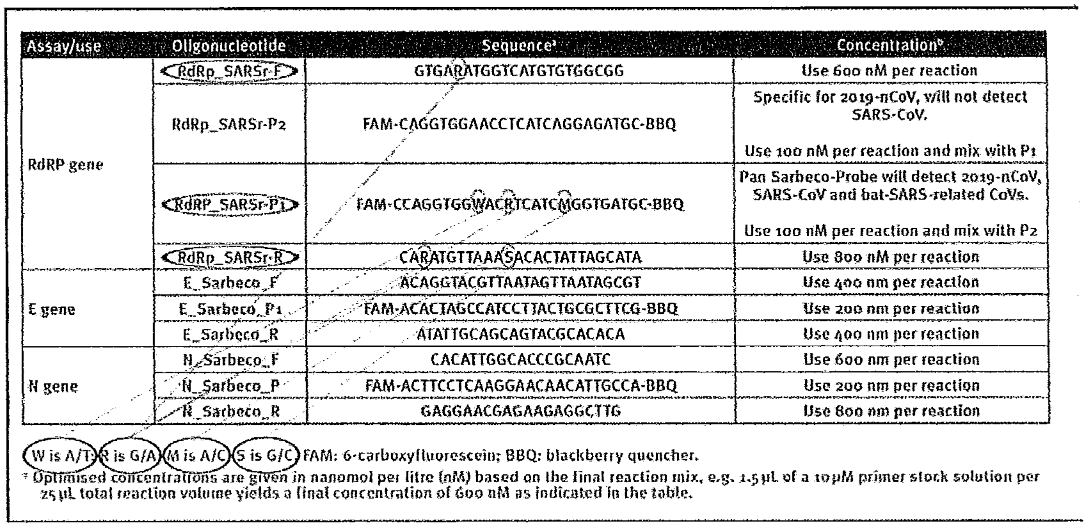
[b] Optimised concentrations are given in nanomol per litre (nM) based on the final reaction mix, e.g. 1.5 µL of a 10 µM primer stock solution per 25 µL total reaction volume yields a final concentration of 600 nM as indicated in the table.

1b) Unspecified ("Wobbly") primer and probe sequences

To obtain reproducible and comparable results, it is essential to distinctively define the primer pairs. In the Corman-Drosten paper we observed six unspecified positions, indicated by the letters R, W, M and S (Table 2). The letter W means that at this position there can be

either an A or a T; R signifies there can be either a G or an A; M indicates that the position may either be an A or a C; the letter S indicates there can be either a G or a C on this position. This high number of variants not only is unusual, but it also is highly confusing for laboratories. These six unspecified positions could easily result in the design of several different alternative primer sequences which do not relate to SARS-CoV-2 (2 distinct RdRp_SARSr_F primers + 8 distinct RdRp_SARS_P1 probes + 4 distinct RdRp_SARSr_R). The design variations will inevitably lead to results that are not even SARS CoV-2 related. Therefore, the confusing unspecific description in the Corman-Drosten paper is not suitable as a Standard Operational Protocol. These unspecified positions should have been designed unequivocally.
These wobbly sequences have already created a source of concern in the field and resulted in a Letter to the Editor authored by Pillonel et al. [8] regarding blatant errors in the described sequences. These errors are self-evident in the Corman et al. supplement as well.

Table 2: Primers and probes (adapted from Corman-Drosten paper; unspecified ("Wobbly") nucleotides in the primers are highlighted)



Assay/use	Oligonucleotide	Sequence[a]	Concentration[b]
RdRP gene	RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG	Use 600 nM per reaction
	RdRp_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ	Specific for 2019-nCoV, will not detect SARS-CoV. Use 100 nM per reaction and mix with P1
	RdRP_SARSr-P1	FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ	Pan Sarbeco-Probe will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs. Use 100 nM per reaction and mix with P2
	RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA	Use 800 nM per reaction
E gene	E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Use 400 nm per reaction
	E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BBQ	Use 200 nm per reaction
	E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Use 400 nm per reaction
N gene	N_Sarbeco_F	CACATTGGCACCCGCAATC	Use 600 nm per reaction
	N_Sarbeco_P	FAM-ACTTCCTCAAGGAACAACATTGCCA-BBQ	Use 200 nm per reaction
	N_Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Use 800 nm per reaction

W is A/T; R is G/A; M is A/C; S is G/C; FAM: 6-carboxyfluorescein; BBQ: blackberry quencher.
[a] Optimised concentrations are given in nanomol per litre (nM) based on the final reaction mix, e.g. 1.5 μL of a 10 μM primer stock solution per 25 μL total reaction volume yields a final concentration of 600 nM as indicated in the table.

The WHO-protocol (Figure 1), which directly derives from the Corman-Drosten paper, concludes that in order to confirm the presence of SARS-CoV-2, two control genes (the E-and the RdRp-genes) must be identified in the assay. It should be noted, that the RdPd-gene has one uncertain position ("wobbly") in the forward-primer (R=G/A), two uncertain positions in the reverse-primer (R=G/A; S=G/C) and it has three uncertain positions in the RdRp-probe (W=A/T; R=G/A; M=A/C). So, two different forward primers, four different reverse primers, and eight distinct probes can be synthesized for the RdPd-gene. Together, there are 64 possible combinations of primers and probes!

The Corman-Drosten paper further identifies a third gene which, according to the WHO protocol, was not further validated and deemed unnecessary:

> *"Of note, the N gene assay also performed well but was not subjected to intensive further validation because it was slightly less sensitive."*

This was an unfortunate omission as it would be best to use all three gene PCRs as confirmatory assays, and this would have resulted in an almost sufficient virus RNA detection diagnostic tool protocol. Three confirmatory assay-steps would at least minimize-out errors & uncertainties at every fold-step in regards to "Wobbly"-spots. (Nonetheless, the protocol would still fall short of any "good laboratory practice", when factoring in all the other design-errors).

As it stands, the N gene assay is regrettably neither proposed in the WHO-recommendation (Figure 1) as a mandatory and crucial third confirmatory step, nor is it emphasized in the Corman-Drosten paper as important optional reassurance "for a routine workflow" (Table 2).

Consequently, in nearly all test procedures worldwide, merely 2 primer matches were used instead of all three. This oversight renders the entire test-protocol useless with regards to delivering accurate test-results of real significance in an ongoing pandemic.

Figure 1: The N-Gene confirmatory-assay is neither emphasized as necessary third step in the official WHO Drosten-Corman protocol-recommendation below [8] nor is it required as a crucial step for higher test-accuracy in the Eurosurveillance publication.

> **Background**
> We used known SARS- and SARS-related coronaviruses (bat viruses from our own studies as well as literature sources) to generate a non-redundant alignment (excerpts shown in Annex). We designed candidate diagnostic RT-PCR assays before release of the first sequence of 2019-nCoV. Upon sequence release, the following assays were selected based on their matching to 2019-nCoV as per inspection of the sequence alignment and initial evaluation (Figures 1 and 2).
>
> **All assays can use SARS-CoV genomic RNA as positive control. Synthetic control RNA for 2019-nCoV E gene assay is available via EVAg. Synthetic control for 2019-nCoV RdRp is expected to be available via EVAg from Jan 21st onward.**
>
> **First line screening assay: E gene assay**
> **Confirmatory assay: RdRp gene assay**

1c) Erroneous GC-content (discussed in 2c, together with annealing temperature (Tm))

1d) Detection of viral genes

RT-PCR is not recommended for primary diagnostics of infection. This is why the RT-PCR Test used in clinical routine for detection of COVID-19 is not indicated for COVID-19 diagnosis on a regulatory basis.

"Clinicians need to recognize the enhanced accuracy and speed of the molecular diagnostic techniques for the diagnosis of infections, but also to understand their limitations. Laboratory results should always be interpreted in the context of the clinical presentation of the patient, and appropriate site, quality, and timing of specimen collection are required for reliable test results". [9]

However, it may be used to help the physician's differential diagnosis when he or she has to discriminate between different infections of the lung (Flu, Covid-19 and SARS have very similar symptoms). For a confirmative diagnosis of a specific virus, at least 3 specific primer pairs must be applied to detect 3 virus-specific genes. Preferably, these target genes should be located with the greatest distance possible in the viral genome (opposite ends included).

Although the Corman-Drosten paper describes 3 primers, these primers only cover roughly half of the virus' genome. This is another factor that decreases specificity for detection of intact COVID-19 virus RNA and increases the quote of false positive test results.

Therefore, even if we obtain three positive signals (i.e. the three primer pairs give 3 different amplification products) in a sample, this does not prove the presence of a virus. A better primer design would have terminal primers on both ends of the viral genome. This is because the whole viral genome would be covered and three positive signals can better discriminate between a complete (and thus potentially infectious) virus and fragmented viral genomes (without infectious potency). In order to infer anything of significance about the infectivity of the virus, the Orf1 gene, which encodes the essential replicase enzyme of SARS-CoV viruses, should have been included as a target (Figure 2). The positioning of the targets in the region of the viral genome that is most heavily and variably transcribed is another weakness of the protocol.

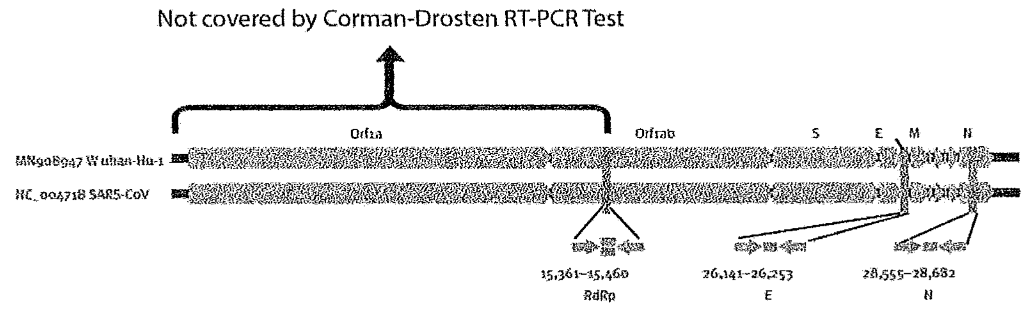
Kim et al. demonstrate a highly variable 3' expression of subgenomic RNA in Sars-CoV-2 [23]. These RNAs are actively monitored as signatures for asymptomatic and non-infectious patients [10]. It is highly questionable to screen a population of asymptomatic people with qPCR primers that have 6 base pairs primer-dimer on the 3 prime end of a primer (Figure 3).

Apparently the WHO recommends these primers. We tested all the wobble derivatives from the Corman-Drosten paper with Thermofisher's primer dimer web tool [11]. The RdRp forward primer has 6bp 3prime homology with Sarbeco E Reverse. At high primer concentrations this is enough to create inaccuracies.

Of note: There is a perfect match of one of the N primers to a clinical pathogen (Pantoea), found in immuno-compromised patients. The reverse primer hits Pantoea as well but not in the same region (Figure 3).

These are severe design errors, since the test cannot discriminate between the whole virus and viral fragments. The test cannot be used as a diagnostic for SARS-viruses.

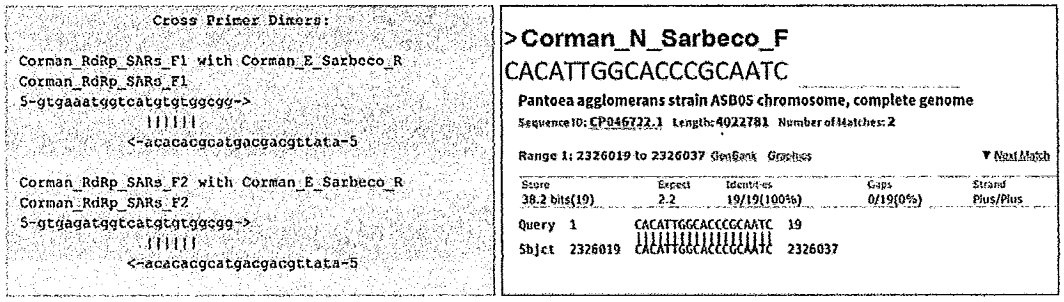
Figure 2: Relative positions of amplicon targets on the SARS coronavirus and the 2019 novel coronavirus genome. ORF: open reading frame; RdRp: RNA-dependent RNA polymerase. Numbers below amplicon are genome positions according to SARS-CoV, NC_004718 [1];



E: envelope protein gene; *M*: membrane protein gene; N: nucleocapsid protein gene; ORF: open reading frame; RdRp: RNA-dependent RNA polymerase gene; S: spike protein gene.

Numbers below amplicons are genome positions according to SARS-CoV, GenBank NC_004718.

Figure 3: A test with Thermofischer's primer dimer web tool reveals that the RdRp forward primer has a 6bp 3`prime homology with Sarbeco E Reverse (left box). Another test reveals that there is a perfect match for one of the N-primers to a clinical pathogen (Pantoea) found in immuno-compromised patients (right box).



```
                 Cross Primer Dimers:

Corman_RdRp_SARs_F1 with Corman_E_Sarbeco_R
Corman_RdRp_SARs_F1
5-gtgaaatggtcatgtgtggcgg->
             ||||||
          <-acacacgcatgacgacgttata-5

Corman_RdRp_SARs_F2 with Corman_E_Sarbeco_R
Corman_RdRp_SARs_F2
5-gtgagatggtcatgtgtggcgg->
             ||||||
          <-acacacgcatgacgacgttata-5
```

>Corman_N_Sarbeco_F

CACATTGGCACCCGCAATC

Pantoea agglomerans strain ASB05 chromosome, complete genome

```
Sequence ID: CP046722.1   Length: 4022781   Number of Matches: 2

Range 1: 2326019 to 2326037  GenBank   Graphics                    ▼ Next Match

Score            Expect   Identities      Gaps        Strand
38.2 bits(19)    2.2      19/19(100%)     0/19(0%)    Plus/Plus

Query  1        CACATTGGCACCCGCAATC  19
                |||||||||||||||||||
Sbjct  2326019  CACATTGGCACCCGCAATC  2326037
```

2. Reaction temperature

2a) DNA melting temperature (>92°).
Adequately addressed in the Corman-Drosten paper.

2b) DNA amplification temperature.
Adequately addressed in the Corman-Drosten paper.

2c) Erroneous GC-contents and Tm
The annealing-temperature determines at which temperature the primer attaches/detaches from the target sequence. For an efficient and specific amplification, GC content of primers should meet a minimum of 40% and a maximum of 60% amplification. As indicated in table 3, three of the primers described in the Corman-Drosten paper are not within the normal range for GC-content. Two primers (RdRp_SARSr_F and RdRp_SARSr_R) have unusual and very low GC-values of 28%-31% for all possible variants of wobble bases, whereas primer E_Sarbeco_F has a GC-value of 34.6% (Table 3 and second panel of Table 3).

It should be noted that the GC-content largely determines the binding to its specific target due to its three hydrogen bonds in base pairing. Thus, the lower the GC-content of the primer, the lower its binding-capability to its specific target gene sequence (i.e. the gene to be detected). This means for a target-sequence to be recognized we have to choose a temperature which is as close as possible to the actual annealing-temperature (best practise-value) for the primer not to detach again, while at the same time specifically selecting the target sequence.

If the Tm-value is very low, as observed for all wobbly-variants of the RdRp reverse primers, the primers can bind non-specifically to several targets, decreasing specificity and increasing potential false positive results.

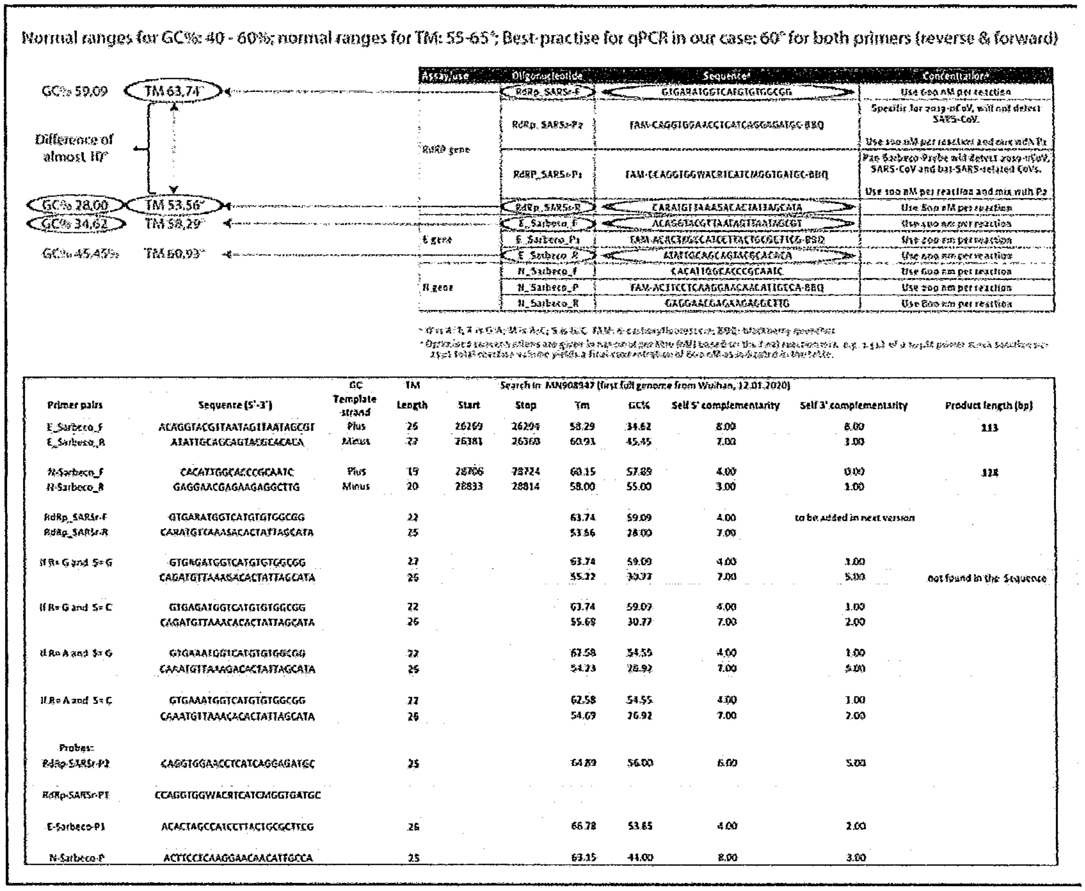
The annealing temperature (Tm) is a crucial factor for the determination of the specificity/accuracy of the qPCR procedure and essential for evaluating the accuracy of qPCR-protocols. Best-practice recommendation: Both primers (forward and reverse) should have an almost similar value, preferably the identical value.

We used the freely available primer design software Primer-BLAST [12, 25] to evaluable the best-practise values for all primers used in the Corman-Drosten paper (Table 3). We attempted to find a Tm-value of 60° C, while similarly seeking the highest possible GC%-value for all primers. A maximal Tm difference of 2° C within primer pairs was considered acceptable. Testing the primer pairs specified in the Corman-Drosten paper, we observed a difference of 10° C with respect to the annealing temperature Tm for primer pair1 (RdRp_SARSr_F and RdRp_SARSr_R). This is a very serious error and makes the protocol useless as a specific diagnostic tool.

Additional testing demonstrated that only the primer pair designed to amplify the N-gene (N_Sarbeco_F and N_Sarbeco_R) reached the adequate standard to operate in a diagnostic test, since it has a sufficient GC-content and the Tm difference between the primers (N_Sarbeco_F and N_Sarbeco_R) is 1.85° C (below the crucial maximum of 2° C difference). Importantly, this is the gene which was neither tested in the virus samples (Table 2) nor emphasized as a confirmatory test. In addition to highly variable melting temperatures and degenerate sequences in these primers, there is another factor impacting specificity of the procedure: the dNTPs (0.4uM) are 2x higher than recommended for a highly specific amplification. There is additional magnesium sulphate added to the reaction as well. This procedure combined with a low annealing temperature can create non-specific amplifications. When additional magnesium is required for qPCR, specificity of the assay should be further scrutinized.

The design errors described here are so severe that it is highly unlikely that specific amplification of SARS-CoV-2 genetic material will occur using the protocol of the Corman-Drosten paper.

Table 3: GC-content of the primers and probes (adapted from Corman-Drosten paper; aberrations from optimized GC-contents are highlighted. Second Panel shows a table-listing of all Primer-BLAST best practices values for all primers and probes used in the Corman-Drosten paper by Prof. Dr. Ulrike Kämmerer & her team.


GC% 59,09
TM 63,74°
Difference of almost 10°
GC% 28,00
TM 53,56°
GC% 34,62
TM 58,29°
GC% 45,45%
TM 60,93°

Normal ranges for GC%: 40 - 60%; normal ranges for TM: 55-65°; Best-practise for qPCR in our case: 60° for both primers (reverse & forward)

Assay/use	Oligonucleotide	Sequence^a	Concentration^b
RdRP gene	RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG	Use 600 nM per reaction
	RdRp_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ	Specific for 2019-nCoV, will not detect SARS-CoV. Use 100 nM per reaction and mix with P1
	RdRP_SARSr-P1	FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ	Pan Sarbeco-Probe will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs. Use 100 nM per reaction and mix with P2
	RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA	Use 800 nM per reaction
E gene	E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Use 400 nm per reaction
	E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BBQ	Use 200 nm per reaction
	E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Use 400 nm per reaction
N gene	N_Sarbeco_F	CACATTGGCACCCGCAATC	Use 600 nm per reaction
	N_Sarbeco_P	FAM-ACTTCCTCAAGGAACAACATTGCCA-BBQ	Use 200 nm per reaction
	N_Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Use 800 nm per reaction

		GC	TM	Search in MN908947 (first full genome from Wuhan, 12.01.2020)						
Primer pairs	Sequence (5'-3')	Template strand	Length	Start	Stop	Tm	GC%	Self 5' complementarity	Self 3' complementarity	Product length (bp)
E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Plus	26	26269	26294	58.29	34.62	8.00	6.00	113
E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Minus	22	26381	26360	60.93	45.45	7.00	3.00	
N-Sarbeco_F	CACATTGGCACCCGCAATC	Plus	19	28706	28724	60.15	57.89	4.00	0.00	128
N-Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Minus	20	28833	28814	58.00	55.00	3.00	1.00	
RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG		22			63.74	59.09	4.00	to be added in next version	
RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA		25			53.56	28.00	7.00		
If R= G and S= G	GTGAGATGGTCATGTGTGGCGG		22			63.74	59.09	4.00	1.00	
	CAGATGTTAAAGACACTATTAGCATA		26			55.72	30.77	7.00	5.00	not found in the Sequence
If R= G and S= C	GTGAGATGGTCATGTGTGGCGG		22			63.74	59.09	4.00	1.00	
	CAGATGTTAAACACACTATTAGCATA		26			55.69	30.77	7.00	2.00	
If R= A and S= G	GTGAAATGGTCATGTGTGGCGG		22			62.58	54.55	4.00	1.00	
	CAAATGTTAAAGACACTATTAGCATA		26			54.73	26.92	7.00	5.00	
If R= A and S= C	GTGAAATGGTCATGTGTGGCGG		22			62.58	54.55	4.00	1.00	
	CAAATGTTAAACACACTATTAGCATA		26			54.09	26.92	7.00	2.00	
Probes:										
RdRp-SARSr-P2	CAGGTGGAACCTCATCAGGAGATGC		25			64.89	56.00	6.00	5.00	
RdRp-SARSr-P1	CCAGGTGGWACRTCATCMGGTGATGC									
E-Sarbeco-P1	ACACTAGCCATCCTTACTGCGCTTCG		26			66.78	53.85	4.00	2.00	
N-Sarbeco-P	ACTTCCTCAAGGAACAACATTGCCA		25			63.15	44.00	8.00	3.00	

3. The number of amplification cycles

It should be noted that there is no mention anywhere in the Corman-Drosten paper of a test being positive or negative, or indeed what defines a positive or negative result. These types of virological diagnostic tests must be based on a SOP, including a validated and fixed number of PCR cycles (Ct value) after which a sample is deemed positive or negative. The maximum reasonably reliable Ct value is 30 cycles. Above a Ct of 35 cycles, rapidly increasing numbers of false positives must be expected .

PCR data evaluated as positive after a Ct value of 35 cycles are completely unreliable.

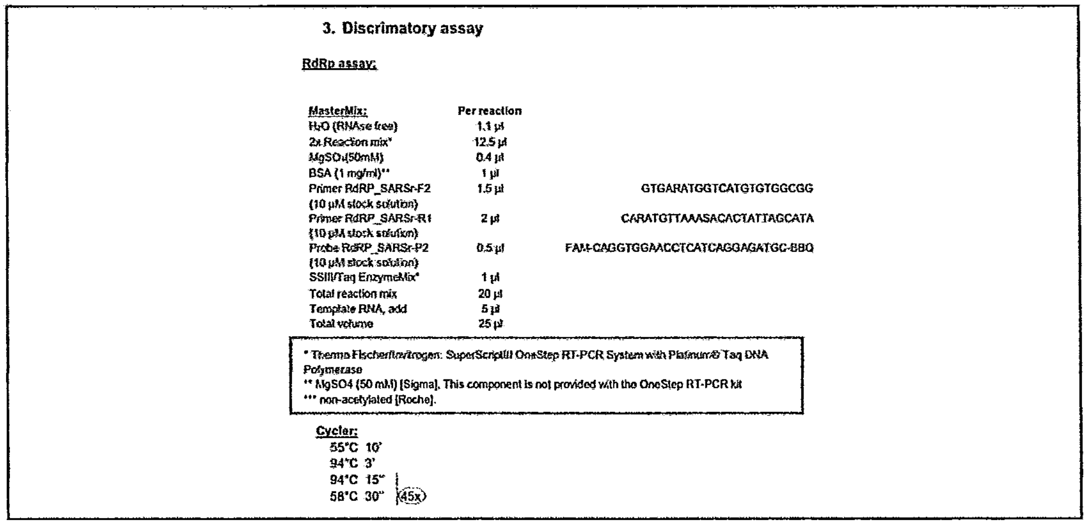
Citing Jaafar et al. 2020 [3]:

"At Ct = 35, the value we used to report a positive result for PCR, <3% of cultures are positive."

In other words, there was no successful virus isolation of SARS-CoV-2 at those high Ct values. Further, scientific studies show that only non-infectious (dead) viruses are detected with Ct values of 35 [22].

Between 30 and 35 there is a grey area, where a positive test cannot be established with certainty. This area should be excluded. Of course, one could perform 45 PCR cycles, as recommended in the Corman-Drosten WHO-protocol (Figure 4), but then you also have to define a reasonable Ct-value (which should not exceed 30). But an analytical result with a Ct value of 45 is scientifically and diagnostically absolutely meaningless (a reasonable Ct-value should not exceed 30). All this should be communicated very clearly. It is a significant mistake that the Corman-Drosten paper does not mention the maximum Ct value at which a sample can be unambiguously considered as a positive or a negative test-result. This important cycle threshold limit is also not specified in any follow-up submissions to date.

Figure 4: RT-PCR Kit recommendation in the official Corman-Drosten WHO-protocol [8]. Only a "Cycler"-value (cycles) is to be found without corresponding and scientifically reasonable Ct (Cutoff-value). This or any other cycles-value is nowhere to be found in the actual Corman-Drosten paper.



3. Discrimatory assay

RdRp assay:

MasterMix:	Per reaction	
H_2O (RNAse free)	1.1 µl	
2x Reaction mix*	12.5 µl	
$MgSO_4$(50mM)	0.4 µl	
BSA (1 mg/ml)**	1 µl	
Primer RdRP_SARSr-F2 (10 µM stock solution)	1.5 µl	GTGARATGGTCATGTGTGGCGG
Primer RdRP_SARSr-R1 (10 µM stock solution)	2 µl	CARATGTTAAASACACTATTAGCATA
Probe RdRP_SARSr-P2 (10 µM stock solution)	0.5 µl	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ
SSIII/Taq EnzymeMix*	1 µl	
Total reaction mix	20 µl	
Template RNA, add	5 µl	
Total volume	25 µl	

* Thermo Fischer/Invitrogen: SuperScript III OneStep RT-PCR System with Platinum® Taq DNA Polymerase
** $MgSO_4$ (50 mM) [Sigma]. This component is not provided with the OneStep RT-PCR kit
*** non-acetylated [Roche].

Cycler:
55°C 10'
94°C 3'
94°C 15"
58°C 30" 45x

4. Biomolecular validations

To determine whether the amplified products are indeed SARS-CoV-2 genes, biomolecular validation of amplified PCR products is essential. For a diagnostic test, this validation is an absolute must.

Validation of PCR products should be performed by either running the PCR product in a 1% agarose-EtBr gel together with a size indicator (DNA ruler or DNA ladder) so that the size of the product can be estimated. The size must correspond to the calculated size of the amplification product. But it is even better to sequence the amplification product. The latter will give 100% certainty about the identity of the amplification product. Without molecular validation one can not be sure about the identity of the amplified PCR products. Considering the severe design errors described earlier, the amplified PCR products can be anything.

Also not mentioned in the Corman-Drosten paper is the case of small fragments of qPCR (around 100bp): It could be either 1,5% agarose gel or even an acrylamide gel.

The fact that these PCR products have not been validated at molecular level is another striking error of the protocol, making any test based upon it useless as a specific diagnostic tool to identify the SARS-CoV-2 virus.

5. Positive and negative controls to confirm/refute specific virus detection.

The unconfirmed assumption described in the Corman-Drosten paper is that SARS-CoV-2 is the only virus from the SARS-like beta-coronavirus group that currently causes infections in humans. The sequences on which their PCR method is based are in silico sequences, supplied by a laboratory in China [23], because at the time of development of the PCR test no control material of infectious ("live") or inactivated SARS-CoV-2 was available to the authors. The PCR test was therefore designed using the sequence of the known SARS-CoV as a control material for the Sarbeco component (Dr. Meijer, co-author Corman-Drosten paper in an email exchange with Dr. Peter Borger) [2].

All individuals testing positive with the RT-PCR test, as described in the Corman-Drosten paper, are assumed to be positive for SARS-CoV-2 infections. There are three severe flaws in their assumption. First, a positive test for the RNA molecules described in the Corman-Drosten paper cannot be equated to "infection with a virus". A positive RT-PCR test merely indicates the presence of viral RNA molecules. As demonstrated under point 1d (above), the Corman-Drosten test was not designed to detect the full-length virus, but only a fragment of the virus. We already concluded that this classifies the test as unsuitable as a diagnostic test for SARS-virus infections.

Secondly and of major relevance, the functionality of the published RT-PCR Test was not demonstrated with the use of a positive control (isolated SARS-CoV-2 RNA) which is an essential scientific gold standard.

Third, the Corman-Drosten paper states:

"To show that the assays can detect other bat-associated SARS-related viruses, we used the E gene assay to test six bat-derived faecal samples available from Drexler et al. [...] und Muth et al. [...]. These virus-positive samples stemmed from European rhinolophid bats. Detection of these phylogenetic outliers within the SARS-related CoV clade suggests that all Asian viruses are likely to be detected. This would, theoretically, ensure broad sensitivity even in case of multiple independent acquisitions of variant viruses from an animal reservoir."

This statement demonstrates that the E gene used in RT-PCR test, as described in the Corman-Drosten paper, is not specific to SARS-CoV-2.

The E gene primers also detect a broad spectrum of other SARS viruses.

The genome of the coronavirus is the largest of all RNA viruses that infect humans and they all have a very similar molecular structure. Still, SARS-CoV1 and SARS-CoV-2 have two highly specific genetic fingerprints, which set them apart from the other coronaviruses. First, a unique fingerprint-sequence (KTFPPTEPKKDKKKK) is present in the N-protein of SARS-CoV and SARS-CoV-2 [13,14,15]. Second, both SARS-CoV1 and SARS-CoV2 do not contain the HE protein, whereas all other coronaviruses possess this gene [13, 14]. So, in order to specifically detect a SARS-CoV1 and SARS-CoV-2 PCR product the above region in the N gene should have been chosen as the amplification target. A reliable diagnostic test should focus on this specific region in the N gene as a confirmatory test. The PCR for this N gene was not further validated nor recommended as a test gene by the Drosten-Corman paper, because of being "not so sensitive" with the SARS-CoV original probe [1].

Furthermore, the absence of the HE gene in both SARS-CoV1 and SARS-CoV-2 makes this gene the ideal negative control to exclude other coronaviruses. The Corman-Drosten paper does not contain this negative control, nor does it contain any other negative controls. The

PCR test in the Corman-Drosten paper therefore contains neither a unique positive control nor a negative control to exclude the presence of other coronaviruses. This is another major design flaw which classifies the test as unsuitable for diagnosis.

6. Standard Operational Procedure (SOP) is not available

There should be a Standard Operational Procedure (SOP) available, which unequivocally specifies the above parameters, so that all laboratories are able to set up the identical same test conditions. To have a validated universal SOP is essential, because it facilitates data comparison within and between countries. It is very important to specify all primer parameters unequivocally. We note that this has not been done. Further, the Ct value to indicate when a sample should be considered positive or negative is not specified. It is also not specified when a sample is considered infected with SARS-CoV viruses. As shown above, the test cannot discern between virus and virus fragments, so the Ct value indicating positivity is crucially important. This Ct value should have been specified in the Standard Operational Procedure (SOP) and put on-line so that all laboratories carrying out this test have exactly the same boundary conditions. It points to flawed science that such an SOP does not exist. The laboratories are thus free to conduct the test as they consider appropriate, resulting in an enormous amount of variation. Laboratories all over Europe are left with a multitude of questions; which primers to order? which nucleotides to fill in the undefined places? which Tm value to choose? How many PCR cycles to run? At what Ct value is the sample positive? And when is it negative? And how many genes to test? Should all genes be tested, or just the E and RpRd gene as shown in Table 2 of the Corman-Drosten paper? Should the N gene be tested as well? And what is their negative control? What is their positive control?

The protocol as described is unfortunately very vague and erroneous in its design that one can go in dozens of different directions. There does not appear to be any standardization nor an SOP, so it is not clear how this test can be implemented.

7. Consequences of the errors described under 1-5: false positive results.

The RT-PCR test described in the Corman-Drosten paper contains so many molecular biological design errors (see 1-5) that it is not possible to obtain unambiguous results. It is inevitable that this test will generate a tremendous number of so-called "false positives". The definition of false positives is a negative sample, which initially scores positive, but which is negative after retesting with the same test. False positives are erroneous positive test-results, i.e. negative samples that test positive. And this is indeed what is found in the Corman-Drosten paper. On page 6 of the manuscript PDF the authors demonstrate, that even under well-controlled laboratory conditions, a considerable percentage of false positives is generated with this test:

"In four individual test reactions, weak initial reactivity was seen however they were negative upon retesting with the same assay. These signals were not associated with any particular virus, and for each virus with which initial positive reactivity occurred, there were other samples that contained the same virus at a higher concentration but did not test positive. Given the results from the extensive technical qualification described above, it was concluded that this initial reactivity was not due to chemical instability of real-time PCR probes and most probably to handling issues caused by the rapid introduction of new diagnostic tests and controls during this evaluation study." [1]

The first sentence of this excerpt is clear evidence that the PCR test described in the Corman-Drosten paper generates false positives. Even under the well-controlled conditions of the state-of-the-art Charité-laboratory, 4 out of 310 primary-tests are false positives per definition. Four negative samples initially tested positive, then were negative upon retesting. This is the classical example of a false positive. In this case the authors do not identify them as false positives, which is intellectually dishonest.

Another telltale observation in the excerpt above is that the authors explain the false positives away as "handling issues caused by the rapid introduction of new diagnostic tests". Imagine the laboratories that have to introduce the test without all the necessary information normally described in an SOP.

8. The Corman-Drosten paper was not peer-reviewed

Before formal publication in a scholarly journal, scientific and medical articles are traditionally certified by "peer review." In this process, the journal's editors take advice from various experts ("referees") who have assessed the paper and may identify weaknesses in its assumptions, methods, and conclusions. Typically a journal will only publish an article once the editors are satisfied that the authors have addressed referees' concerns and that the data presented supports the conclusions drawn in the paper." This process is as well described for Eurosurveillance [16].

The Corman-Drosten paper was submitted to Eurosurveillance on January 21st 2020 and accepted for publication on January 22nd 2020. On January 23rd 2020 the paper was online. On January 13th 2020 version 1-0 of the protocol was published at the official WHO website [17], updated on January 17th 2020 as document version 2-1 [18], even before the Corman-Drosten paper was published on January 23rd at Eurosurveillance.

Normally, peer review is a time-consuming process since at least two experts from the field have to critically read and comment on the submitted paper. In our opinion, this paper was not peer-reviewed. Twenty-four hours are simply not enough to carry out a thorough peer review. Our conclusion is supported by the fact that a tremendous number of very serious design flaws were found by us, which make the PCR test completely unsuitable as a diagnostic tool to identify the SARS-CoV-2 virus. Any molecular biologist familiar with RT-PCR design would have easily observed the grave errors present in the Corman-Drosten paper before the actual review process. We asked Eurosurveillance on October 26th 2020 to send us a copy of the peer review report. To date, we have not received this report and in a letter dated November 18th 2020, the ECDC as host for Eurosurveillance declined to provide access without providing substantial scientific reasons for their decision. On the contrary, they write that "disclosure would undermine the purpose of scientific investigations." [24].

9. Authors as the editors

A final point is one of major concern. It turns out that two authors of the Corman-Drosten paper, Christian Drosten and Chantal Reusken, are also members of the editorial board of this journal [19]. Hence there is a severe conflict of interest which strengthens suspicions that the paper was not peer-reviewed. It has the appearance that the rapid publication was possible simply because the authors were also part of the editorial board at Eurosurveillance. This practice is categorized as compromising scientific integrity.

SUMMARY CATALOGUE OF ERRORS FOUND IN THE PAPER

The Corman-Drosten paper contains the following specific errors:

1. There exists no specified reason to use these extremely high concentrations of primers in this protocol. The described concentrations lead to increased nonspecific bindings and PCR product amplifications, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

2. Six unspecified wobbly positions will introduce an enormous variability in the real world laboratory implementations of this test; the confusing nonspecific description in the Corman-Drosten paper is not suitable as a Standard Operational Protocol making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

3. The test cannot discriminate between the whole virus and viral fragments. Therefore, the test cannot be used as a diagnostic for intact (infectious) viruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus and make inferences about the presence of an infection.

4. A difference of 10° C with respect to the annealing temperature Tm for primer pair1 (RdRp_SARSr_F and RdRp_SARSr_R) also makes the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

5. A severe error is the omission of a Ct value at which a sample is considered positive and negative. This Ct value is also not found in follow-up submissions making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

6. The PCR products have not been validated at the molecular level. This fact makes the protocol useless as a specific diagnostic tool to identify the SARS-CoV-2 virus.

7. The PCR test contains neither a unique positive control to evaluate its specificity for SARS-CoV-2 nor a negative control to exclude the presence of other coronaviruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

8. The test design in the Corman-Drosten paper is so vague and flawed that one can go in dozens of different directions; nothing is standardized and there is no SOP. This highly questions the scientific validity of the test and makes it unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

9. Most likely, the Corman-Drosten paper was not peer-reviewed making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

10. We find severe conflicts of interest for at least four authors, in addition to the fact that two of the authors of the Corman-Drosten paper (Christian Drosten and Chantal Reusken) are members of the editorial board of Eurosurveillance. A conflict of interest was added on July 29 2020 (Olfert Landt is CEO of TIB-Molbiol; Marco Kaiser is senior researcher at GenExpress and serves as scientific advisor for TIB-Molbiol), that was not declared in the original version (and still is missing in the PubMed version); TIB-Molbiol is the company which was "the first" to produce PCR kits (Light Mix) based on the protocol published in the Corman-Drosten manuscript, and according to their own words, they distributed these PCR-test kits before the publication was even submitted [20]; further, Victor Corman & Christian Drosten failed to mention their second affiliation: the commercial test laboratory "Labor Berlin". Both are responsible for the virus diagnostics there [21] and the company operates in the realm of real time PCR-testing.

In light of our re-examination of the test protocol to identify SARS-CoV-2 described in the Corman-Drosten paper we have identified concerning errors and inherent fallacies which render the SARS-CoV-2 PCR test useless.

CONCLUSION

The decision as to which test protocols are published and made widely available lies squarely in the hands of Eurosurveillance. A decision to recognise the errors apparent in the Corman-Drosten paper has the benefit to greatly minimise human cost and suffering going forward.

Is it not in the best interest of Eurosurveillance to retract this paper? Our conclusion is clear. In the face of all the tremendous PCR-protocol design flaws and errors described here, we conclude: There is not much of a choice left in the framework of scientific integrity and responsibility.

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Author's Affiliations:

1) Dr. Pieter Borger (MSc, PhD), Molecular Genetics, W+W Research Associate, Lörrach, Germany

2) Rajesh Kumar Malhotra (Artist Alias: Bobby Rajesh Malhotra), Former 3D Artist / Scientific Visualizations at CeMM - Center for Molecular Medicine of the Austrian Academy of Sciences (2019-2020), University for Applied Arts - Department for Digital Arts Vienna, Austria

3) Dr. Michael Yeadon BSs(Hons) Biochem Tox U Surrey, PhD Pharmacology U Surrey. Managing Director, Yeadon Consulting Ltd, former Pfizer Chief Scientist, United Kingdom

4) Dr. Clare Craig MA, (Cantab) BM, BCh (Oxon), FRCPath, United Kingdom

5) Kevin McKernan, BS Emory University, Chief Scientific Officer, founder Medical Genomics, engineered the sequencing pipeline at WIBR/MIT for the Human Genome Project, Invented and developed the SOLiD sequencer, awarded patents related to PCR, DNA Isolation and Sequencing, USA

6) Prof. Dr. Klaus Steger, Department of Urology, Pediatric Urology and Andrology, Molecular Andrology, Biomedical Research Center of the Justus Liebig University, Giessen, Germany

7) Dr. Paul McSheehy (BSc, PhD), Biochemist & Industry Pharmacologist, Loerrach, Germany

8) Dr. Lidiya Angelova, MSc in Biology, PhD in Microbiology, Former researcher at the National Institute of Allergy and Infectious Diseases (NIAID), Maryland, USA

9) Dr. Fabio Franchi, Former Dirigente Medico (M.D) in an Infectious Disease Ward, specialized in "Infectious Diseases" and "Hygiene and Preventive Medicine", Società Scientifica per il Principio di Precauzione (SSPP), Italy

10) Dr. med. Thomas Binder, Internist and Cardiologist (FMH), Switzerland

11) Prof. Dr. med. Henrik Ullrich, specialist Diagnostic Radiology, Chief Medical Doctor at the Center for Radiology of Collm Oschatz-Hospital, Germany

12) Prof. Dr. Makoto Ohashi, Professor emeritus, PhD in Microbiology and Immunology, Tokushima University, Japan

13) Dr. Stefano Scoglio, B.Sc. Ph.D., Microbiologist, Nutritionist, Italy

14) Dr. Marjolein Doesburg-van Kleffens (MSc, PhD), specialist in Laboratory Medicine (clinical chemistry), Maasziekenhuis Pantein, Beugen, The Netherlands

15) Dr. Dorothea Gilbert (MSc, PhD), PhD Environmental Chemistry and Toxicology. DGI Consulting Services, Oslo, Norway

16) Dr. Rainer J. Klement, PhD. Department of Radiation Oncology, Leopoldina Hospital Schweinfurt, Germany

17) Dr. Ruth Schruefer, PhD, human genetics/ immunology, Munich, Germany,

18) Dra. Berber W. Pieksma, General Practitioner, The Netherlands

19) Dr. med. Jan Bonte (GJ), Consultant Neurologist, The Netherlands

20) Dr. Bruno H. Dalle Carbonare (Molecular biologist), IP specialist, BDC Basel, Switzerland

21) Dr. Kevin P. Corbett, MSc Nursing (Kings College London) PhD (London South Bank) Social Sciences (Science & Technology Studies) London, England, United Kingdom

22) Prof. Dr. Ulrike Kämmerer, specialist in Virology / Immunology / Human Biology / Cell Biology, University Hospital Würzburg, Germany

Author's Contributions:

PB: Planned and conducted the analyses and research, conceptualising the manuscript.

BRM: Planned and conducted the research, conceptualising the figures and manuscript.

MY: Conducted the analyses and research.

KMcK: Conducted the analyses and research, conceptualized the manuscript.

KS: Conducted the analyses and research.

PMcS: Proofreading the analyses and research.

LA: Proofreading the analyses and research.

FF: Proofreading the analyses and research.

TB: Proofreading the analyses and research.

HU: Proofreading the analyses and research.

MO: Proofreading the analyses and research.

SS: Proofreading the analyses and research.

MDvK: Proofreading the analyses and research.

DG: Proofreading the analyses and research.

RJK: Proofreading the analyses and research.

RS: Proofreading the analyses and research, and the manuscript.

BWK: Proofreading the analyses and research.

RvV: Proofreading the analyses and research.

JB: Proofreading the analyses and research.

KC: Proofreading the analyses and research.

UK: Planned and conducted the analyses and research, conceptualising the manuscript.

Additional Proof-Readers:

Saji N Hameed, Environmental Informatics, University of Aizu, Tsuruga, Ikki-machi, Aizuwakamatsu-shi, Fukushima, Japan

Howard R. Steen, MA Chem. Eng. Cantab, Former Research Manager, Germany

Review Report by an International Consortium of Scientists in Life Sciences (ICSLS) - Corman-Drosten *et al.*, Eurosurveillance 2020 (Updated: 29.11.2020)

False Positive Covid Tests Will Extend Unjustified Lockdowns, Fauci Admits 'Miniscule' Accuracy

By Jefferey Jaxen

Whether you live in the USA or most of Europe, one thing remains true: Covid-19 testing regimes are being aggressively pushed onto populations.

Masked populations in some countries have been told (again) they cannot leave their homes. Economies and personal lives remain stunted and manipulated by government edicts. The ticket to a 'new normal' freedom has been dangled: A PCR Covid test.

In February, according to NPR, an internal review at the Centers for Disease Control and Prevention (CDC) confirmed Covid tests could be wrong 33% of the time – but CDC sent them out across the country anyway.

But that's not the whole story of the CDC's issues with quality control. Timothy Stenzel, director of the Food and Drug Administration's (FDA) Office of InVitro Diagnostics and Radiological Health, visited the CDC's respiratory disease lab and found sloppy lab protocols.

Months latter, Stenzel's own agency was disgraced as they approved tests for Emergency Use Authorization without even the most basic vetting. The FDA's policy required only that companies attest their product was valid and labeled as unapproved. The result was a flood of 170 tests—many from China, which only complicated the problem.

That's bad, but here's the *real* story. The 'mainstream' narrative was allowed to change on August 29th, when the NY Times published *Your Coronavirus Test Is Positive. Maybe It Shouldn't Be.*

The article touched on ideas that, up until then, were only considered to be spread by 'conspiracy theorists' peddling censorable 'misinformation.' The issues: false positives and no way of determining the amount of virus in someone's body. The test provides little if any sense of how contagious a person may be. If they even *have* the virus to begin with!

The polymerase chain reaction (or PCR test), amplifies viral RNA using multiple cycles to produce a detectable amount. The cycle threshold (CT) value is the number of cycles necessary to spot the virus. The false positives come down to a question of testing cycles.

From the *NY Times*: "*Most tests set the limit at 40, a few at 37...The C.D.C.'s own calculations suggest that it is extremely difficult to detect any live virus in a sample above a threshold of 33 cycles. Officials at some state labs said the C.D.C. had not asked them to note threshold values or to share them with contact-tracing organizations.*"

Dr. Anthony Fauci recently echoed the previous findings, long-reported by the independent media and other lone voices. Despite open knowledge of false positives from high testing cycles, Dr. Fauci made the unfathomable claim that it's now "Sorta evolving into a bit of a standard." Why is he now openly admitting what has been known for years?

Fauci added, "*If you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule.*" Got that, ***minuscule***. Fauci didn't stop there. "*You almost never can culture virus from a 37 threshold cycle. So I think if someone does come in with a 37...38, even 36, ya gotta say, ya know, it's just dead nucleotides. Period.*"

Even a Fauci admits any PCR results above 35 cycles are false – which is probably most of the UK results driving policy. Listen to Fauci from July saying you can't culture live virus above 35, it's just dead RNA – and yet UI bases lockdywn in this fraud. pic.twitter.com/iumVKoLdEy
— Jeff Nelson (@vegsource) November 2, 2020

After hearing Fauci, the next logical question for populations being held under lock and key is: *What cycle thresholds are being run on the current Covid tests*?

Investigative journalist Jon Rappoport writes, "*What Fauci failed to say on the video is: the FDA, which authorizes the test for public use, recommends the test should be run up to 40 cycles. Not 35. Therefore, all labs in the US that follow the FDA guideline are knowingly or unknowingly participating in fraud.*"

The NY Times investigation confirmed that officials at the Wadsworth Center, New York's state lab identified positive tests based on a threshold of 40 cycles. Likewise in Massachusetts, "from 85 to 90 percent of people who tested positive in July with a cycle threshold of 40 would have been deemed negative if the threshold were 30 cycles," writes the NY Times.

This is not just an American phenomenon. In August in the U.K., Tom Jefferson, Carl Heneghan and others at the Centre for Evidence Based Medicine asked Are you infectious if you have a positive PCR test result for COVID-19?

The team cited several studies and concluded, "*limited data of variable quality that PCR results per se are unlikely to predict viral culture from human samples....The relation with infectiousness is unclear and more data are needed on this. If this is not understood, PCR results may lead to restrictions for large groups of people who do not present an infection risk.*"

On two separate occasions, Jefferson and Heneghan attempted to warn UK Prime Minister Boris Johnson against the lockdown strategy. They called for a national program of testing quality control to ensure accurate, precise and consistent results, among other common sense ideas. The two had said they searched in vain for evidence that the tests in use in the UK have been independently validated. They further called for transparency around data showing how sensitive the laboratory processes have been.

In the UK, the reality of false positives is urgent. Johnson and his gaggle of tone deaf officials are rolling out mandatory testing for all residents of four towns and counting. The DailyMail reports, “around 1,000 soldiers will be deployed” to force more than 100,000 people to get tested. Those who have questioned the move are being banned from social media.

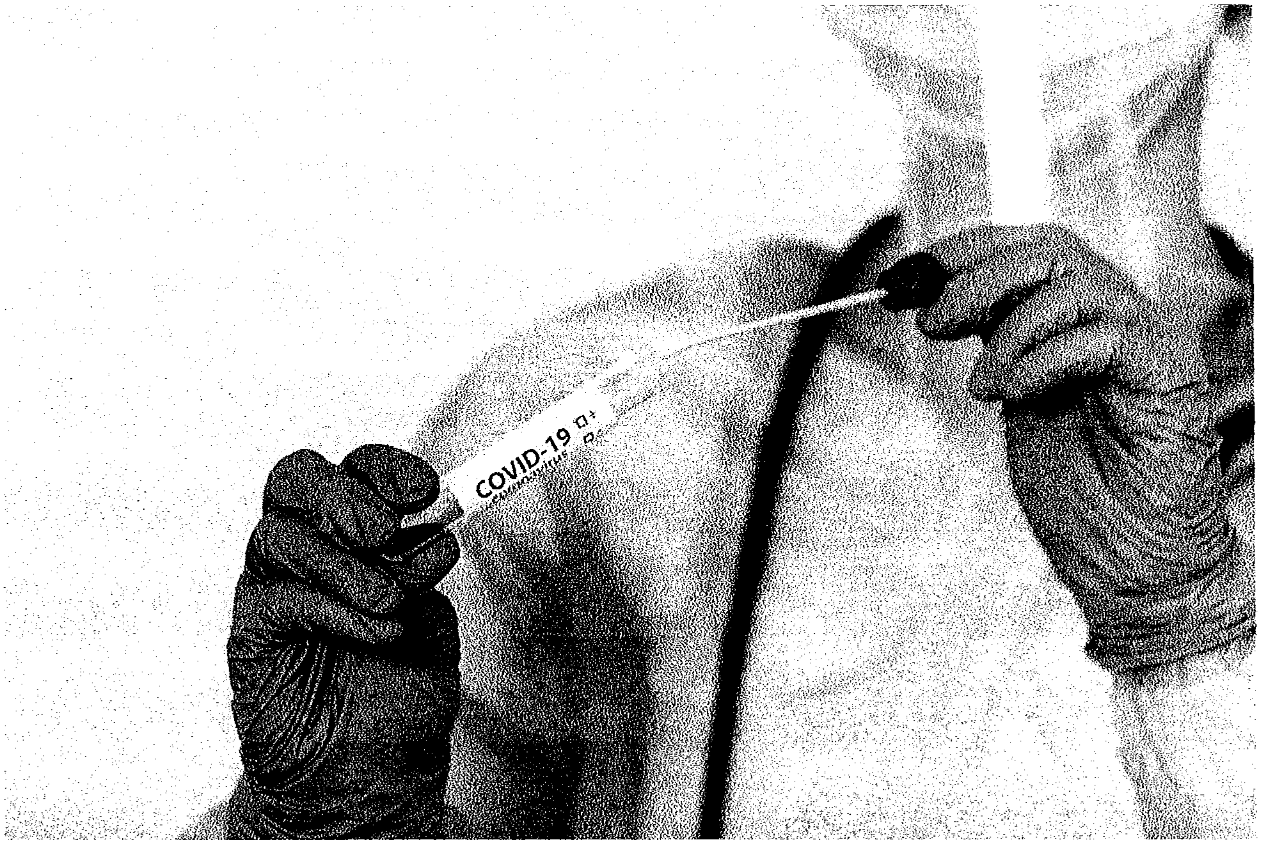
After looking at the mass testing proposal in Liverpool, Bristol public health consultant Angela Raffle told *The Guardian*, “Experience with screening tells us that if you embark on a screening programme without having carefully evaluated it first, without a proper quality-assured pathway, without certainty of test performance in field settings, without full information for participants, and without the means to ensure that the intervention needed for those with positive results does indeed take place, the result is an expensive mess that does more harm than good,”

With mortality rates well below anything seen at the height of the ‘first wave,’ mass testing programs are sure to artificially inflate [false] cases. This will give the government its much-needed excuse to continue the unscientific, harmful and inhuman lockdown treatments of their populations. Expect multilevel revolt in the weeks...or maybe even days...as civil disobedience escalates.

El fraude de las PCR al descubierto (1)

ALO Política y Derechos Ciudadanos | Pruebas Diagnósticas diciembre 1, 2020

Nuestra entrada de hoy está dedicada a la mayor noticia que se ha producido en este año desde la declaratoria de pandemia en lo relacionado con la controvertibilidad científica del fenómeno Covid19 y su corolario de medidas sanitarias y administrativas de enorme calado en el devenir de nuestras sociedades. Se trata de la publicación de una Revisión científica por pares publicada este pasado 26 de Noviembre sobre el artículo científico publicado el 23 de enero de 2020 (unos días después del artículo que señalaba desde Wuhan el hallazgo del nuevo coronavirus), firmado por el Dr Drosten, el Dr. Corman y otros 22 científicos internacionales y por el cual se presentaba al Mundo la supuesta prueba apta para la detección del virus SarsCoV2 y el protocolo para la diagnosis de base de la enfermedad Covid 19. La importancia de esta Revisión reside en el hecho de que es sobre la base de ese documento y del test que pretende presentar y protocolizar, producido en apenas unos días y no validado por pares, sobre lo que se ha apoyado argumentalmente la retahíla de declaraciones, medidas y estadísticas extendida por organismos internacionales, estatales y medios de comunicación de masas: la RT-PCR es la piedra angular de la narrativa covídica. La Revisión está compuesta por una Carta en la que se solicita la retirada del Diario Europeo de Vigilancia epidemiológica (Eurosurveillance) del artículo de Drosten y su equipo, así como de una explicación del por qué de esta solicitud, que remite al artículo extenso y en el que se develan 10 fraudes contenidos en la publicación de Drosten, Corman et al. Hemos organizado la entrada en 3 partes: la Carta, firmada por 17 profesionales de las ciencias de la vida; una síntesis del artículo de Revisión; y el catálogo que resume los 10 errores principales. Invitamos a los lectores de ABRE LOS OJOS a revisar con detenimiento este documento y difundir esta entrada por todos los medios disponibles. Nos jugamos la verdad.



1. LA CARTA

26 de noviembre de 2020,
Para: Consejo Editorial Eurosurveillance
Centro Europeo para la Prevención y el Control de las Enfermedades (ECDC)
El Boulevard 40 de Gustav III
16973 Solna
Suecia
Sujeto: Revisión externa y solicitud de retirada del documento de Corman et al, publicado en Eurosurveillance el 23 de enero de 2020.

Estimado Comité editorial de Eurosurveillance,

Nosotros, un consorcio internacional de científicos de Ciencias de la vida, escribimos esta carta en respuesta al artículo «Detección del coronavirus del 2019 (2019-nCoV) por RT-PCR en tiempo real» publicado en Eurosurveillance (23 de enero de 2020) y co-escrito por Victor M Corman , Olfert Landt , Marco Kaiser , Richard Molenkamp, Adam Meijer, Daniel KW Chu, Tobias Bleicker , Sebastian Brünink, Julia Schneider , Marie Luisa Schmidt , Daphne GJC Mulders , Bart L Haagmans , Bas van der Veer ,

Sharon van den Brink, Lisa Wijsman, Gabriel Goderski, Jean-Louis Romette, Joanna Ellis, Maria Zambon, Malik Peiris, Herman Goossens, Chantal Reusken, Marion PG Koopmans, y Christian Drosten.
En el presente documento (en adelante denominado «documento Corman-Drosten»), publicado por «Eurosurveillance» el 23 de enero de 2020, se describe un método de RT-PCR para detectar el nuevo coronavirus (también conocido como SARS-CoV2). Tras un examen minucioso, **nuestro consorcio internacional de científicos especializados en ciencias de la vida determinó que el documento de Corman-Drosten presentaba graves deficiencias en cuanto a su diseño biomolecular y metodológico**. Se pueden encontrar argumentos científicos detallados en nuestro examen «Examen externo por pares de la prueba RTPCR para detectar el SARS-CoV2 revela 10 defectos científicos importantes a nivel molecular y metodológico: consecuencias para los resultados positivos falsos», que presentamos para su publicación en Eurosurveillance.
Además, la fecha de presentación y la fecha de aceptación de este documento son el 21 y el 22 de enero, respectivamente. Teniendo en cuenta los graves errores de diseño y metodología de la prueba RT-PCR publicada por «Eurosurveillance», esto plantea la preocupación de si el documento fue sometido a alguna revisión por pares.
No se ha cumplido una solicitud anterior de nuestra parte (Dr. P. Borger; correo electrónico 26/10/2020) a los editores de «Eurosurveillance» para que proporcionen el informe de revisión por pares del documento Corman-Drosten. Hemos adjuntado su respuesta por correo electrónico (con fecha 18/11/2020) indicando que no desea revelar información importante para resolver este enigma.

Confiamos en que usted tomará nuestras objeciones científicas seriamente y reconocerá que no hay otra alternativa que aceptar nuestra solicitud de retirar el documento Corman-Drosten.

Sinceramente,
Dr. Pieter Borger (MSc, PhD), Genética Molecular, Investigador Asociado de W+W, Lörrach, Alemania

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Prof. Dr. Ulrike Kämmerer, especialista en Virología / Inmunología / Biología Humana / Biología Celular, Hospital Universitario de Würzburg, Alemania

Prof. Dr. Klaus Steger, Departamento de Urología, Urología Pediátrica y Andrología, Andrología Molecular, Centro de Investigación Biomédica de la Universidad Justus Liebig, Giessen, Alemania

Prof. Dr. Makoto Ohashi, Profesor emérito, Doctor en Microbiología e Inmunología, Universidad de Tokushima, Japón

Prof. Dr. med. Henrik Ullrich, especialista en Radiología Diagnóstica, Médico Jefe del Centro de Radiología del Hospital Collm Oschatz, Alemania

Rajesh K. Malhotra (Artista Alias: Bobby Rajesh Malhotra), Ex Artista 3D / Visualizaciones Científicas en el CeMM – Centro de Medicina Molecular de la Academia Austríaca de Ciencias (2019-2020), Universidad de Artes Aplicadas – Departamento de Artes Digitales Viena, Austria

Dr. Michael Yeadon BSs(Hons) Biochem Tox U Surrey, PhD Pharmacology U Surrey. Director Gerente de Yeadon Consulting Ltd, ex Jefe Científico de Pfizer, Reino Unido

Dr. Kevin P. Corbett, MSc Enfermería (Kings College London) PhD (London South Bank) Ciencias Sociales (Estudios de Ciencia y Tecnología) Londres, Inglaterra, Reino Unido

Dra. Clare Craig MA, (Cantab) BM, BCh (Oxon), FRCPath, Reino Unido

Kevin McKernan, BS Universidad de Emory, Director Científico, fundador de Medical Genomics, diseñó la tubería de secuenciación en WIBR/MIT para el Proyecto del Genoma Humano, Inventó y desarrolló el secuenciador SOLiD, otorgó patentes relacionadas con la PCR, el aislamiento y la secuenciación del ADN, EE.UU.

Dra. Lidiya Angelova, MSc en Biología, PhD en Microbiología, Ex investigadora del Instituto Nacional de Alergia y Enfermedades Infecciosas (NIAID), Maryland, EE.UU.

Dr. Fabio Franchi, ex Dirigente Médico (M.D.) en una sala de enfermedades infecciosas, especializado en «Enfermedades infecciosas» y «Higiene y medicina preventiva», Società Scientifica per il Principio di Precauzione (SSPP), Italia

Dr. med. Thomas Binder, Internista y Cardiólogo (FMH), Suiza

Dr. Stefano Scoglio, Doctor en Ciencias, Microbiólogo, Nutricionista, Italia

Dr. Paul McSheehy (BSc, PhD), bioquímico y farmacólogo industrial, Loerrach, Alemania

Dra. Marjolein Doesburg-van Kleffens, (MSc, PhD), especialista en Medicina de Laboratorio (química clínica), Maasziekenhuis Pantein, Beugen, Países Bajos

Dra. Dorothea Gilbert (MSc, PhD), PhD Química Ambiental y Toxicología. DGI Consulting Services, Oslo, Noruega

Nov 26th 2020

To:
Editorial Board Eurosurveillance
European Centre for Disease Prevention and Control (ECDC)
Gustav III:s Boulevard 40
16973 Solna
Sweden

Subject: External Review and request to retract the paper of Corman et al, published in Eurosurveillance January 23, 2020.

Dear editorial board Eurosurveillance,

We, an international consortium of life-science scientists, write this letter in response to the article "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR" published in Eurosurveillance (January 23rd, 2020) and co-authored by Victor M Corman, Olfert Landt, Marco Kaiser, Richard Molenkamp, Adam Meijer, Daniel KW Chu, Tobias Bleicker, Sebastian Brünink, Julia Schneider, Marie Luisa Schmidt, Daphne GJC Mulders, Bart L Haagmans, Bas van der Veer, Sharon van den Brink, Lisa Wijsman, Gabriel Goderski, Jean-Louis Romette, Joanna Ellis, Maria Zambon, Malik Peiris, Herman Goossens, Chantal Reusken, Marion PG Koopmans, and Christian Drosten.

This paper (hereafter referred to as "Corman-Drosten paper"), published by "Eurosurveillance" on 23 January 2020, describes an RT-PCR method to detect the novel Corona virus (also known as SARS-CoV2). After careful consideration, our international consortium of Life Science scientists found the Corman-Drosten paper is severely flawed with respect to its biomolecular and methodological design. A detailed scientific argumentations can be found in our review "External peer review of the RTPCR test to detect SARS-CoV2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results", which we herewith submit for publication in Eurosurveillance.

Further, the submission date and acceptance date of this paper are January 21st and January 22nd, respectively. Considering the severe errors in design and methodology of the RT-PCR test published by "Eurosurveillance", this raises the concern whether the paper was subjected to peer-review at all.

A previous request from our side (Dr. P. Borger, email 26/10/2020) to the editors of "Eurosurveillance" to provide the peer review report of the Corman-Drosten paper has not been complied with. We have enclosed your email reply (dated 18/11/2020) indicating that you do not wish to disclose important information to solve this conundrum.

We are confident that you will take our scientific objections seriously and recognize that there is no alternative but to accept our request to retract the Corman-Drosten paper.

Sincerely,

Dr. Pieter Borger (MSc, PhD), Molecular Genetics, W+W Research Associate, Lörrach, Germany, email address retracted

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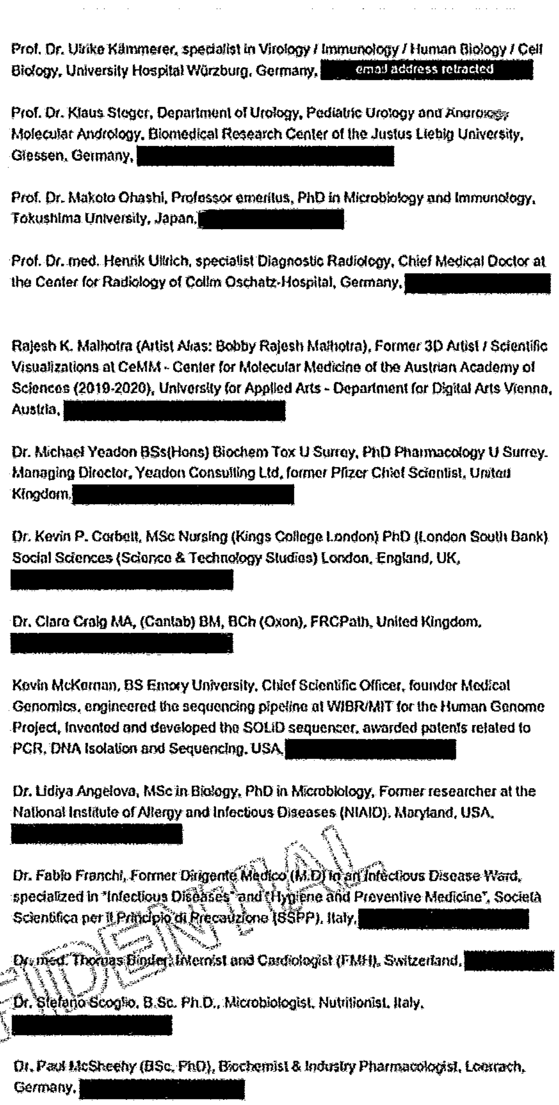

Prof. Dr. Ulrike Kämmerer, specialist in Virology / Immunology / Human Biology / Cell Biology, University Hospital Würzburg, Germany, email address retracted

Prof. Dr. Klaus Steger, Department of Urology, Pediatric Urology and Andrology, Molecular Andrology, Biomedical Research Center of the Justus Liebig University, Giessen, Germany, [redacted]

Prof. Dr. Makoto Ohashi, Professor emeritus, PhD in Microbiology and Immunology, Tokushima University, Japan, [redacted]

Prof. Dr. med. Henrik Ullrich, specialist Diagnostic Radiology, Chief Medical Doctor at the Center for Radiology of Collm Oschatz-Hospital, Germany, [redacted]

Rajesh K. Malhotra (Artist Alias: Bobby Rajesh Malhotra), Former 3D Artist / Scientific Visualizations at CeMM - Center for Molecular Medicine of the Austrian Academy of Sciences (2019-2020), University for Applied Arts - Department for Digital Arts Vienna, Austria, [redacted]

Dr. Michael Yeadon BSs(Hons) Biochem Tox U Surrey, PhD Pharmacology U Surrey. Managing Director, Yeadon Consulting Ltd, former Pfizer Chief Scientist, United Kingdom, [redacted]

Dr. Kevin P. Corbett, MSc Nursing (Kings College London) PhD (London South Bank) Social Sciences (Science & Technology Studies) London, England, UK, [redacted]

Dr. Clare Craig MA, (Cantab) BM, BCh (Oxon), FRCPath, United Kingdom, [redacted]

Kevin McKernan, BS Emory University, Chief Scientific Officer, founder Medical Genomics, engineered the sequencing pipeline at WIBR/MIT for the Human Genome Project, Invented and developed the SOLiD sequencer, awarded patents related to PCR, DNA Isolation and Sequencing, USA, [redacted]

Dr. Lidiya Angelova, MSc in Biology, PhD in Microbiology, Former researcher at the National Institute of Allergy and Infectious Diseases (NIAID), Maryland, USA, [redacted]

Dr. Fabio Franchi, Former Dirigente Medico (M.D) in an Infectious Disease Ward, specialized in "Infectious Diseases" and "Hygiene and Preventive Medicine", Società Scientifica per il Principio di Precauzione (SSPP), Italy, [redacted]

Dr. med. Thomas Binder, Internist and Cardiologist (FMH), Switzerland, [redacted]

Dr. Stefano Scoglio, B.Sc. Ph.D., Microbiologist, Nutritionist, Italy, [redacted]

Dr. Paul McSheehy (BSc, PhD), Biochemist & Industry Pharmacologist, Loerrach, Germany, [redacted]

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2. SÍNTESIS DEL ESTUDIO (traducido del documento completo en inglés, consultable aquí)

En la publicación titulada «Detección del nuevo coronavirus de 2019 (2019-nCoV) mediante RT-PCR en tiempo real» (Eurosurveillance 25(8) 2020) los autores presentan un flujo de trabajo de diagnóstico y un protocolo de RT-qPCR para la detección y el diagnóstico de 2019-nCoV (ahora conocido como SARS-CoV-2), que afirman haber validado, así como una sólida metodología de diagnóstico para su uso en laboratorios de salud pública.

A la luz de todas las consecuencias resultantes de esta misma publicación para las sociedades de todo el mundo, un grupo de investigadores independientes realizó un examen punto por punto de la mencionada publicación en el que 1) se verificaron de manera cruzada todos los componentes del diseño del ensayo presentado, 2) se evaluaron las recomendaciones del protocolo RT-qPCR con respecto a las buenas prácticas de laboratorio, y 3) se examinaron los parámetros en relación con la literatura científica pertinente que abarca el campo.

El protocolo RT-qPCR publicado para la detección y el diagnóstico de 2019-nCoV y el manuscrito adolecen de numerosos errores técnicos y científicos, entre ellos un diseño insuficiente del cebador, un protocolo RT-qPCR problemático e insuficiente y la ausencia de una validación precisa de la prueba. Ni la prueba presentada ni el propio manuscrito cumplen los requisitos para una publicación científica aceptable. Además, no se mencionan los graves conflictos de intereses de los autores. Por último, el plazo muy breve entre la presentación y la aceptación de la publicación (24 horas) significa que en este caso no se realizó un proceso sistemático de revisión por pares o que la calidad fue deficiente. Proporcionamos pruebas convincentes de varias insuficiencias, errores y fallas científicas.

Considerando los defectos científicos y metodológicos presentados aquí, confiamos en que el consejo editorial de Eurosurveillance no tenga otra opción que retractarse de la publicación.

En el presente documento se mostrarán numerosos y graves defectos del documento de Corman-Drosten, cuya importancia ha llevado a un diagnóstico erróneo en todo el mundo de las infecciones atribuidas al SARS-CoV-2 y asociadas a la enfermedad COVID-19. Nos enfrentamos a rigurosos cierres que han destruido la vida y los medios de subsistencia de muchas personas, el acceso limitado a la educación y estas restricciones impuestas por los gobiernos de todo el mundo son un ataque directo a los derechos básicos de las personas y a sus libertades personales, lo que provoca daños colaterales para economías enteras a escala mundial.

Hay diez problemas fatales en el documento de Corman-Drosten que esbozaremos y explicaremos con mayor detalle en las siguientes secciones.

El primero y más importante es que el nuevo Coronavirus SARS-CoV-2 (en la publicación denominada 2019-nCoV y en febrero de 2020 denominada SARS-CoV-2 por un consorcio internacional de expertos en virus) se basa en secuencias in silico (teóricas), suministradas por un laboratorio de China [1], porque en ese momento no se disponía de material de control del SARS-CoV-2 infeccioso («vivo») o inactivado ni de ARN genómico aislado del virus. Hasta la fecha, la autoría no ha realizado ninguna validación basada en virus aislados del SARS-CoV-2 o en el ARN completo del mismo. Según Corman y otros..:

"Nos propusimos desarrollar y desplegar una metodología de diagnóstico robusta para su uso en laboratorios de salud pública sin disponer de material del virus". [1]

En este caso, la atención debe centrarse en los dos objetivos declarados: a) el desarrollo y b) el despliegue de una prueba de diagnóstico para su uso en los laboratorios de salud pública. Estos objetivos no pueden alcanzarse sin disponer de material viral real (por ejemplo, para determinar la carga viral infecciosa). En cualquier caso, sólo un protocolo con la máxima precisión puede ser el objetivo obligatorio y primario en cualquier escenario - resultado de esta magnitud. La determinación de la carga viral crítica es una información obligatoria, y es responsabilidad del grupo de Christian Drosten realizar estos experimentos y proporcionar los datos cruciales.

Sin embargo, estas secuencias in silico se utilizaron para desarrollar una metodología de prueba RT-PCR para identificar el virus mencionado. Este modelo se basó en el supuesto de que el nuevo virus es muy similar al SARS-CoV de 2003, ya que ambos son beta-coronavirus.

Por lo tanto, la prueba de PCR se diseñó utilizando la secuencia genómica del SARS-CoV como material de control para el componente Sarbeco; lo sabemos por nuestra comunicación personal por correo electrónico con [2] uno de los coautores del documento de Corman-Drosten. Este método para modelar el SARS-CoV-2 fue descrito en el documento de Corman-Drosten de la siguiente manera:

"El establecimiento y la validación de un flujo de trabajo de diagnóstico para la detección del 2019-nCoV y la confirmación específica, diseñado en ausencia de

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aislamientos de virus disponibles o de muestras de pacientes originales. El diseño y la validación fueron posibles gracias a la estrecha relación genética con el SARS-CoV de 2003, y con la ayuda del uso de la tecnología del ácido nucleico sintético".

La Reacción en Cadena de la Polimerasa de Transcripción Inversa (RT-PCR) es una importante tecnología biomolecular para detectar rápidamente fragmentos raros de ARN, que se conocen de antemano. En el primer paso, las moléculas de ARN presentes en la muestra se transcriben de forma inversa para producir ADNc. A continuación, el ADNc se amplifica en la reacción en cadena de la polimerasa utilizando un par de cebadores específicos y una enzima de ADN polimerasa termoestable. La tecnología es altamente sensible y su límite de detección es teóricamente 1 molécula de ADNc. La especificidad de la PCR está altamente influenciada por errores de diseño biomolecular.

3. CATÁLOGO RESUMIDO DE LOS ERRORES ENCONTRADOS EN EL DOCUMENTO

El documento de Corman-Drosten contiene los siguientes errores específicos:

1. No existe una razón específica para utilizar estas concentraciones extremadamente altas de cebadores en este protocolo. Las concentraciones descritas conducen a un aumento de los enlaces inespecíficos y a amplificaciones del producto de la PCR, lo que hace que la prueba no sea adecuada como herramienta de diagnóstico específica para identificar el virus del SARS-CoV-2.
2. La confusa descripción inespecífica que figura en el documento de Corman-Drosten no es adecuada como protocolo operacional estándar, lo que hace que la prueba no sea apropiada como instrumento específico de diagnóstico para identificar el virus del SARS-CoV-2.
3. La prueba no puede discriminar entre el virus completo y los fragmentos virales. Por lo tanto, la prueba no puede utilizarse como diagnóstico de virus intactos (infecciosos), lo que hace que la prueba no sea adecuada como herramienta de diagnóstico específica para identificar el virus del SARS-CoV-2 y hacer inferencias sobre la presencia de una infección.
4. Una diferencia de 10° C con respecto a la temperatura de recocido Tm para el par de cebadores1 (RdRp_SARSr_F y RdRp_SARSr_R)

también hace que la prueba no sea adecuada como instrumento de diagnóstico específico para identificar el virus del SARS-CoV-2.

5. Un error grave es la omisión de un valor de Ct en el que una muestra se considera positiva y negativa. Este valor Ct tampoco se encuentra en las presentaciones de seguimiento, lo que hace que la prueba no sea adecuada como instrumento específico de diagnóstico para identificar el virus del SRAS-CoV-2.
6. Los productos de la PCR no han sido validados a nivel molecular. Este hecho hace que el protocolo sea inútil como herramienta de diagnóstico específica para identificar el virus del SARS-CoV-2.
7. La prueba de PCR no contiene ni un control positivo único para evaluar su especificidad para el SARS-CoV-2 ni un control negativo para excluir la presencia de otros coronavirus, lo que hace que la prueba sea inútil como herramienta de diagnóstico específica para identificar el virus del SARS-CoV-2.
8. El diseño de la prueba en el documento de Corman-Drosten es tan vago y defectuoso que se puede ir en docenas de direcciones diferentes; nada está estandarizado y no hay ningún procedimiento operativo estándar. Esto cuestiona enormemente la validez científica de la prueba y la hace inadecuada como herramienta de diagnóstico específica para identificar el virus del SARS-CoV-2.
9. Lo más probable es que el documento de Corman-Drosten no haya sido revisado por pares, lo que hace que la prueba no sea adecuada como herramienta de diagnóstico específica para identificar el virus del SARS-CoV-2.
10. Encontramos graves conflictos de intereses para al menos cuatro autores, además del hecho de que dos de los autores del artículo de Corman-Drosten (Christian Drosten y Chantal Reusken) son miembros del consejo editorial de Eurosurveillance. El 29 de julio de 2020 se añadió un conflicto de intereses (Olfert Landt es el director general de TIB-Molbiol; Marco Kaiser es investigador principal de GenExpress y sirve como asesor científico de TIB-Molbiol), que no se declaró en la versión original (y que sigue faltando en la versión de PubMed); TIB-Molbiol es la compañía que fue «la primera» en producir kits de PCR (Light Mix) basados en el protocolo publicado en el manuscrito de Corman-Drosten, y según sus propias palabras,

distribuyeron estos kits de prueba de PCR antes de que la publicación fuera siquiera presentada [20]; además, Victor Corman & Christian Drosten no mencionaron su segunda afiliación: el laboratorio comercial de pruebas «Labor Berlin». Ambos son responsables del diagnóstico del virus allí [21] y la compañía opera en el ámbito de las pruebas de PCR en tiempo real.

https://abrelosojos.xyz/cuestiones-importantes/pruebas-diagnosticas/el-fraude-de-las-pcr-al-descubierto/

El fraude de las PCR al descubierto (2)

ALO Pruebas Diagnósticas | Cuestiones Importantes diciembre 7, 2020

Los hisopados para diagnóstico de Covid no son fiables. A la noticia difundida por ALO sobre el Informe científico presentado en Alemania contra el Informe Drosten (creador del cebador en el que se basa la RT-PCR aplicada en todo el mundo), se le suman evidencias halladas en Italia por el equipo del Dr. Stefano Scoglio. El que fuera candidato a Premio Nobel de Medicina en 2018 ha demostrado la falta de fiabilidad de los hisopados realizados para diagnosticar la enfermedad. Los datos de «nuevos casos» Covid19 que han servido de fundamento para las declaratorias de estado de emergencia, los confinamientos y cierres, y las cuarentenas individuales y grupales y el porte obligatorio de mascarilla, habrían perdido su base científica de confirmarse los hallazgos de Scoglio, que han servido de base a varias demandas colectivas.

La Codacons (Coordinadora italiana por la defensa del medio-ambiente y los derechos de los consumidores) y la Asociación Italiana de Derechos de los Pacientes han presentado el pasado 16 de noviembre una denuncia ante nueve fiscalías de Sicilia, entre ellas las de Palermo, Catania, Siracusa, Ragusa, Caltanissetta, Enna, Agrigento, Trapani y Messina. El objetivo es pedir la apertura de investigaciones por fraude, fraude agravado para la obtención de recursos públicos, falsedad ideológica y homicidio culposo. La denuncia está fundamentada en la declaración conjunta firmada por el Dr. Fabio Franchi Doctor, Infectólogo Experto en Virología, la Dra. Antonietta Gatti Científica Experta en Nanopatología, el Dr. Stefano Montanari, Farmacéutico, Investigador Científico y Nanopatólogo, y el Prof. Stefano Scoglio, Investigador Científico, Candidato al Premio Nobel de Medicina 2018, en su calidad de expertos e investigadores científicos. El equipo ha constatado que los resultados de los hisopos carecen casi absolutamente de fiabilidad. La continuación del uso de estos hisopos, a partir de los cuales se obtienen datos útiles para determinar las declaratorias de estado de emergencia, la cuarentena individual o de grupo, los cierres y las limitaciones impuestas, desde las escuelas hasta las familias, no tiene ninguna base científica.

«Los hisopados Covid-19 – dice el profesor Stefano Scoglio – producen hasta un 95% de falsos positivos: certificados por el Instituto Superior de Salud». El hisopado para detectar la presencia del Coronavirus, faríngeo o nasal, no tendría valor diagnóstico. «Esto implica – se lee en la nota emitida por Codacons – que todavía no hay un marcador específico del virus y por lo tanto no hay un estándar que pueda hacer que los hisopados sean fiables. Detrás del alto número de hisopados falsamente positivos – continúa la nota – también podría ocultarse un gran negocio hospitalario».
Según Guido Bertolaso. Ex jefe de protección civil, los hospitales tienen interés en acumular pacientes de Covid por las altas compensaciones que se dan por las hospitalizaciones.
Por su parte, el abogado que encabeza la acción prejudicial, Carmelo Sardella, aclara que se solicita en el texto de la demanda la incautación probatoria de los hisopos de Covid-19 presentes en el territorio, para llevar a cabo un peritaje adecuado sobre las diversas pruebas en circulación para verificar la validez del hisopado como herramienta para hacer un diagnóstico de SARS-CoV-2". «También es importante seguir la pista de los dispositivos falsificados comercializados ilegalmente – continúa Sardella – y verificar que los ensayos se utilizan de forma coherente con el uso previsto, así como verificar el cumplimiento de todas las demás condiciones de validez de los ensayos».
El Dr. Scoglio ya venía advirtiendo desde hace dos meses sobre la escasa fiabilidad de esta prueba . En España, la Doctora y Catedrática en Procesos Diagnósticos Clínicos, Maria José Martínez Albarracín, así como el Decano del Colegio de Biólogos de Euskadi, Jon Ander Etxebarría, corroboraron la total inadecuación de la aplicación de esta prueba para diagnosis viral.
Esta serie de denuncias se anticipó a la denuncia presentada por 17 científicos ante el organismo europeo de control y vigilancia epidemiológica, Eurosurveillance, presentada en la misma fecha y de la cual ALO se hizo eco aquí.
Para consultar la noticia original:

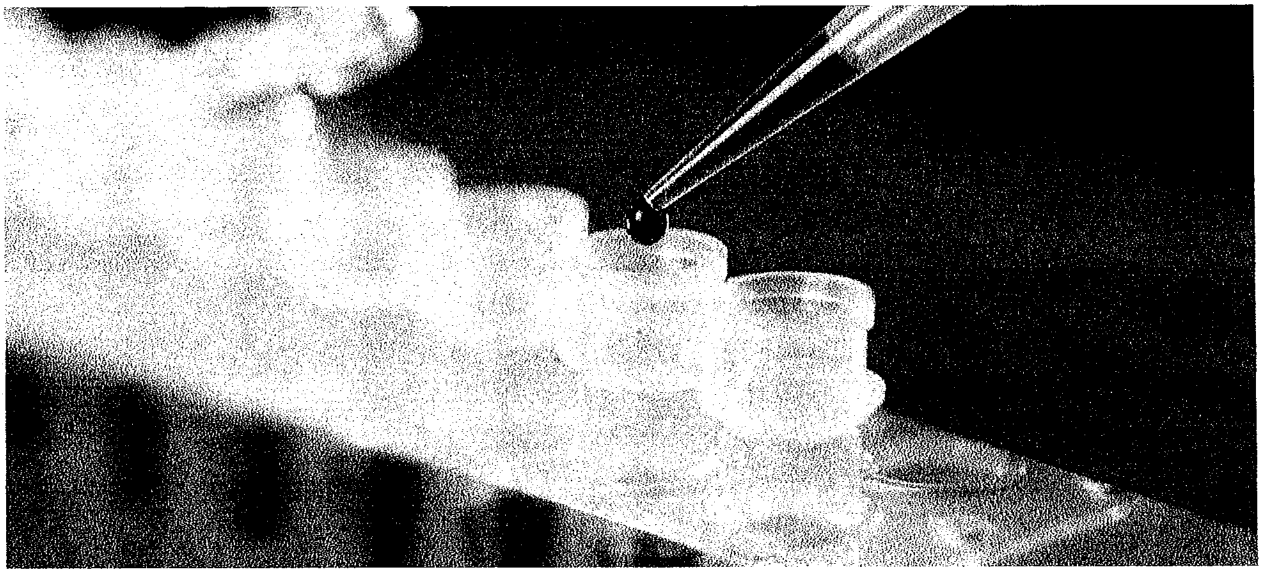
https://abrelosojos.xyz/cuestiones-importantes/el-fraude-de-las-pcr-al-descubierto-2/

El fraude de las PCR al descubierto (3)

ALO Pruebas Diagnósticas | Cuestiones Importantes diciembre 21, 2020

Las evidencias que invalidan la prueba diagnóstica reina en la diagnosis de la Covid19 se acumulan. Al estudio realizado por 23 científicos desmontando la validez del protocolo RT-PCR se le añade una demanda por fraude doloso y conflicto de interés contra el virólogo Drosten, responsable de la gestión de la crisis sanitaria en Alemania y productor del cebador de la prueba. Las implicaciones político-administrativas de este escándalo son tales, que incluso la OMS, que validó e instauró el protocolo de testeo a nivel global, se ha visto obligada a reconocer la escasa fiabilidad de la prueba bajo el número de amplificaciones que se aplica. Sin embargo, las restricciones y la carrera vacunal continúan incólumes y se agudizan, sin que ningún organismo oficial llame a una evaluación de lo sucedido. Ningún medio de comunicación en España ha dado cuenta de ninguna de las 5 evidencias que presentamos a continuación, en lo que parece un bloqueo informativo sin precedentes en la historia de este país.

En nuestras dos entradas anteriores sobre el mismo tema, ALO se hizo eco tanto de los hallazgos clínicos empíricos realizados por el Doctor Scoglio en el sentido de la detección de una enorme proporción de falsos positivos producidos por el sistema de testeo y diagnóstico basado en la RT-PCR, como de los resultados de la Revisión del estudio Drosten/Corman realizada por 23 científicos de primer nivel y en el que se detectaron al menos 10 errores, incoherencias y déficits graves en el test utilizado globalmente para producir las estadísticas epidemiológicas y justificar las medidas sanitarias y de política general que han sido adoptadas desde marzo en todo el globo. En esta entrada vamos a recopilar toda la serie de evidencias que desacreditan la prueba.



Antecedentes

El 23 de enero de 2020, en la revista científica Eurosurveillance, del Centro de Prevención y Control de Enfermedades de la UE, el Dr. Christian Drosten, junto con varios colegas del Instituto de Virología de Berlín en el Hospital Charité, junto con el jefe de una pequeña empresa de biotecnología de Berlín, TIB Molbiol Syntheselabor GmbH, publicó un estudio en el que afirmaba haber desarrollado la primera prueba efectiva para detectar si alguien está infectado con el nuevo coronavirus identificado por primera vez sólo unos días antes en Wuhan. El artículo de Drosten se titulaba «Detección del nuevo coronavirus 2019 (2019-nCoV) por RT-PCR en tiempo real» (Eurosurveillance 25(8) 2020).

Es a partir de este documento sobre el que comienzan tres hechos determinantes: en primer lugar, la asunción de este protocolo como válido y central por parte de la Alemania de Merkel, así como de todos los sistemas de vigilancia y control epidemiológicos y sanitarios europeos y de buena parte del resto del Mundo, y su banalización como instrumento exclusivo de medición y diagnosis para Covid19; en segundo lugar y sobre las cifras proporcionadas por estos sistemas de detección y diagnosis basados en esta RT-PCR, la adopción de una serie de medidas preventivas claramente restrictivas de los derechos ciudadanos (movilidad, trabajo, reunión...) y potencialmente anti-sanitarias (confinamientos generales, cuarentenas indiferenciadas, imposición de mascarillas de seguridad y eficacia cuestionadas); en tercer lugar, la protocolización en el ámbito hospitalario y geriátrico de una serie de praxis (intubaciones de pacientes con cuadros trombocíticos, aislamiento severo y sin cuidados de personas mayores, priorización de la atención sanitaria a personas testeadas positivas y subatención de la población general...) cuyos impactos han podido ser más lesivos que el supuesto daño extraordinario causado por la amenaza que se ha pretendido combatir; por último, la inconsistente validación de la RT-PCR marcó el pistoletazo de salida para la carrera vacunal, emprendida por una serie de grandes farmacéuticas, que usaron igualmente esta prueba como elemento decisivo en los procesos de ingeniería de laboratorio conducentes a la producción de la mayoría de las vacunas, hoy en fase 3 de experimentación pero cuya utilización en la población ya está siendo temerariamente realizada bajo la responsabilidad directa y exclusiva de los Estados.

1. El caso portugués

Este verano, las autoridades sanitarias portuguesas ordenaron a un grupo de cuatro turistas alemanes que se quedara en el hotel guardando cuarentena sanitaria después de que uno de ellos diera positivo por coronavirus en una prueba de PCR (los otros tres fueron etiquetados como contactos cercanos y por lo tanto se fueron igualmente confinados). A principios de este mes, los jueces portugueses confirmaron una decisión de un tribunal inferior que consideró ilegal la cuarentena forzosa. El caso se centró en la fiabilidad (o la falta de ella) de las pruebas de PCR de Covid-19. El veredicto, dictado el 11 de noviembre por el Tribunal de Apelación de Lisboa, siguió a una apelación contra un recurso de hábeas corpus presentado por los ciudadanos alemanes retenidos contra la Autoridad Sanitaria Regional de las Azores. Este organismo había apelado una decisión de un tribunal inferior que había fallado a favor de los turistas, que alegaban que fueron confinados ilegalmente en un hotel sin su consentimiento. Los jueces también dijeron que sólo un médico puede «diagnosticar» a alguien con una enfermedad, y criticaron el hecho de que aparentemente nunca fueron diagnosticados por un galeno. La conclusión de su fallo de 34 páginas fue la siguiente: «A la vista de las pruebas científicas actuales, esta prueba demuestra ser incapaz de determinar más allá de toda duda razonable que tal positividad corresponde, de hecho, a la infección de una persona por el virus del SARS-CoV-2».

Por lo tanto, a los ojos de este tribunal, una prueba positiva no corresponde a un caso Covid. Las dos razones más importantes para esto, dijeron los jueces, son que «la fiabilidad de la prueba depende del número de ciclos utilizados» y que «la fiabilidad de la prueba depende de la carga viral presente».

Más que una evidencia científica directa, la sentencia portuguesa pone de manifiesto la cuestión de la primacía de las libertades y derechos de las personas por sobre la arbitrariedad de medidas sanitarias de no probada eficacia pero que ocasionan de facto situaciones de privación de libertad y sanciones sobre la base de dos presunciones absolutamente falsas: la presunción anticientífica de que una persona con test positivo RT-PCR está infectada y es capaz de transmitir la enfermedad aún sin cursar síntomas; la presunción de que esa hipotética capacidad infecciosa pueda ser potencialmente constitutiva de daño y por ello fundamentar per se una medida preventiva de privación de la libertad.

2. El caso italiano

Como ya publicamos en una entrada anterior de esta serie, el equipo del Profesor Stefano Scoglio halló, tras análisis de varias decenas de hisopados realizados a personas supuestamente infectadas de Covid, que el 95% de los mismos dieron falsos positivos. A mediados de noviembre, dos organizaciones de consumidores y pacientes (CODACONS y Articolo 32) depositaron una denuncia sustentada en los hallazgos del equipo de Scoglio para pedir la apertura de investigaciones por fraude, fraude agravado para la obtención de recursos públicos, falsedad ideológica y homicidio culposo. La misma fue presentada en nueve fiscalías de Sicilia.

3. La revisión externa contra el protocolo Drosten y la demanda

El proceso de comisión del que es muy probablemente el mayor fraude de la historia contemporánea tanto por sus implicaciones sanitarias como económicas y político administrativas está trufado de inconsistencias graves, según la devastadora Revisión externa revisada por pares realizada por 23 científicos del Consorcio Internacional de Científicos de las Ciencias de la Vida (ICSLS), liderada por el Doctor Peter Borger y de la que nos hicimos eco aquí.

Lo primero que llama la atención es el **inusitadamente corto tiempo en el que se elaboró el protocolo RT-PCR del equipo Drosten-Corman**. Como el equipo del Dr Borger señala: «El documento Corman-Drosten fue sometido a Eurosurveillance el 21 de enero de 2020 y aceptado para su publicación el 22 de enero de 2020. El 23 de enero de 2020 el documento estaba publicado en línea». Increíblemente, el protocolo de prueba Drosten, que ya había enviado a la OMS en Ginebra el 17 de enero, fue recomendado oficialmente por la OMS como la prueba mundial para determinar la presencia del coronavirus de Wuhan, incluso antes de que se publicara el documento. Como señalan los científicos denunciantes, para un tema tan complejo e importante para la salud y la seguridad mundiales, no es posible realizar un serio «examen por homólogos» (revisión por pares) en 24 horas por parte de al menos dos expertos en la materia. Como se puede comprobar a través de una simple búsqueda en la BBC y Google Statistics, el 21 de enero hubo un total mundial de 6 muertes atribuidas al virus de Wuhan. En este punto caben muchas preguntas, pero principalmente tres: ¿Por qué el equipo Drosten-Corman asumió la existencia de un reto para los laboratorios de salud pública cuando en ese momento no había pruebas sustanciales que indicaran que el brote estaba más extendido de lo que se pensaba inicialmente?

¿Cómo es posible que el equipo Drosten-Corman pudiera realizar en tan breve espacio de tiempo una prueba determinante para la medición y el control de la que ha sido la mayor amenaza contra la Humanidad, a tenor de los recursos y medidas adoptadas?

¿Cómo es posible que la OMS validara y tomara como referencia este protocolo no revisado por pares y validado sin ningún tipo de reserva ni espacio de revisión por parte de los organismos de control estatales, europeos e internacionales, en un momento en el que no existían aún casos afuera de China?

El Dr Drosten ha sido el coordinador designado por Merkel para la gestión de Covid19 en Alemania.

Un segundo elemento no menor señalado por el equipo denunciante encabezado por el Dr Borger es el que afecta a los **evidentes conflictos de intereses** en la elaboración y comercialización de la prueba RT-PCR. De entre los firmantes del Informe/Protocolo de Drosten, el propio Drosten y una de sus coautoras, la Dra. Chantal Reusken, eran también en el momento de presentación de su Informe/Protocolo miembros del consejo editorial de Eurosurveillance, el organismo europeo encargado de la revisión y validación del mismo. Sin embargo nunca señalaron este hecho. Otro miembro del equipo Drosten, el doctor Olfert Landt, fue el fundador y jefe de la empresa Tib-Molbiol en Berlín, que desarrolló la prueba RT-PCR y que la ha comercializado desde entonces mediante acuerdo con la farmacéutica Roche. Sin embargo, Landt tampoco reveló ese hecho fundamental en el documento de Drosten. (La empresa Roche por cierto, fue la patrocinadora junto al períodico El País el pasado 7 de octubre del evento público en el que el Ministro de Sanidad de España, Salvador Illa, presentó las líneas generales de la nueva política sanitaria española para «la nueva normalidad», como se tituló el evento).

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Salvador Illa en su ponencia en el evento patrocinado por El País y Roche, el pasado 7 de octubre

Si los dos puntos anteriores resultan llamativos, no resultan sin embargo concluyentes per se para evidenciar un fraude. Sintetizamos en este tercer apartado las evidencias que invalidan la metodología en la que se fundamenta el protocolo Drosten-Corman y que demuestran tanto el fraude como la incompetencia científica de sus fabricantes.

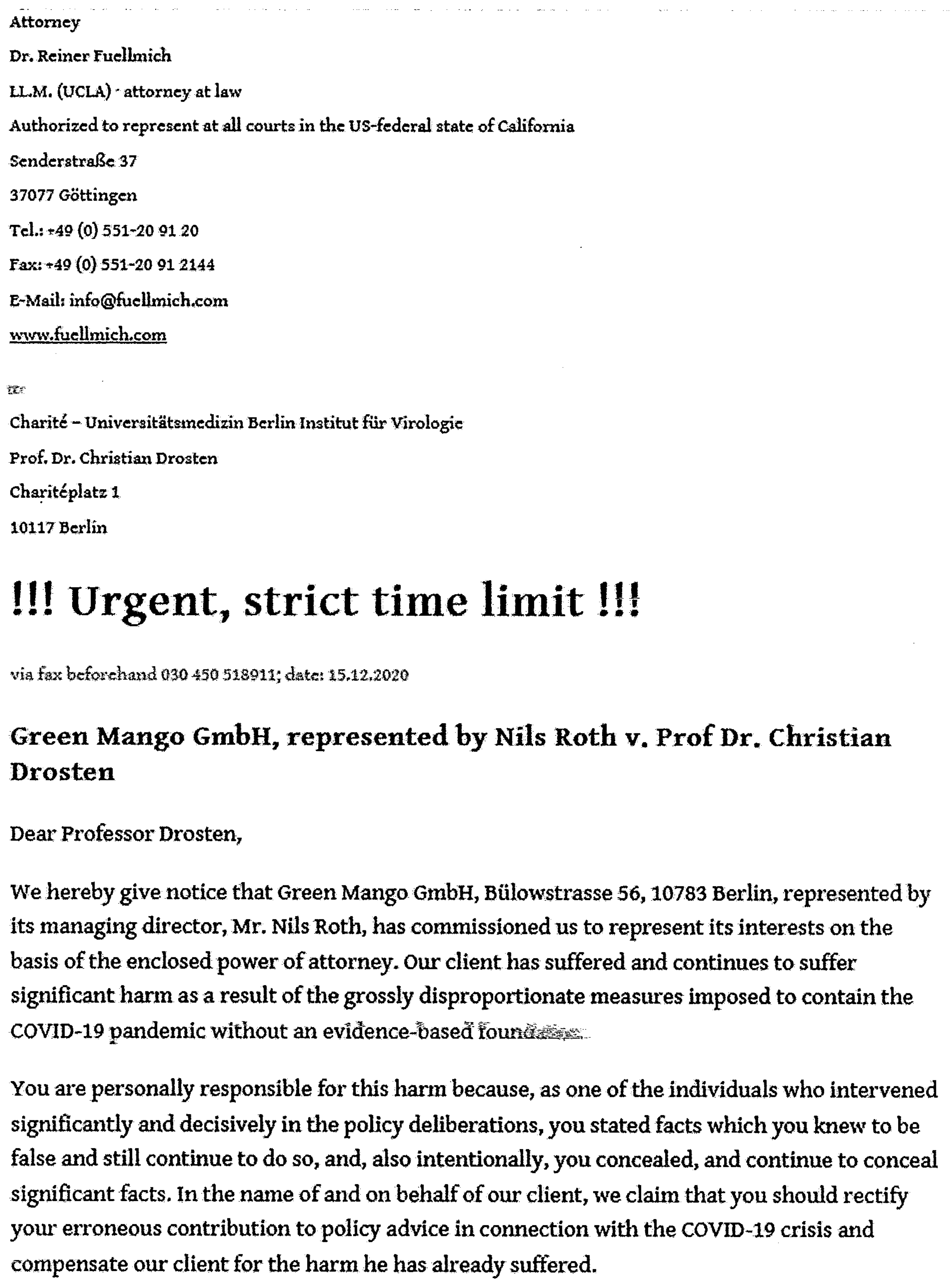
Ausencia de aislamiento del virus como precondición necesaria para diseñar un protocolo efectivo. Se supone que todos los individuos que dan positivo en la prueba RT-PCR, tal y como se describe en el documento de Corman-Drosten, son positivos para las infecciones de SARS-CoV-2. Ahora bien, hay dos defectos graves que invalidan esta suposición. En primer lugar, una prueba positiva para las moléculas de ARN descritas en el documento de Corman-Drosten no puede equipararse a una «infección por un virus». Una prueba RT-PCR positiva sólo indica la presencia de moléculas de ARN virales. La prueba de Corman-Drosten no fue diseñada para detectar el virus en toda su extensión, sino sólo un fragmento del mismo, por lo que el test resulta estructuralmente inadecuado como prueba de diagnóstico para las infecciones del virus del SARS. En segundo lugar aunque de no menor importancia, la funcionalidad de la prueba RT-PCR publicada no se demostró con el uso de un control positivo (ARN aislado del SARS-CoV-2) que es la prueba esencial de fiabilidad (el llamado golden standard) de cualquier prueba de detección viral.

Más que dudosa especificidad . El informe/protocolo del equipo Drosten presentó secuencias confusas y no especificadas de cebadores y sondas, elementos primordiales para el funcionamiento de la prueba. Para confirmar el diagnóstico de un virus específico, se deben aplicar al menos 3 pares de cebadores específicos para detectar 3 genes específicos del virus. Preferiblemente, estos genes objetivo deben estar localizados con la mayor distancia posible en el genoma viral (incluyendo los extremos opuestos). Aunque el documento de Corman-Drosten describe 3 cebadores, estos cebadores sólo cubren aproximadamente la mitad del genoma del virus. Este es otro factor que disminuye la especificidad para la detección del ARN del virus COVID-19 intacto y aumenta la cita de resultados de pruebas falsos positivos. Por lo tanto, aunque obtengamos tres señales positivas (es decir, los tres pares de cebadores dan 3 productos de amplificación diferentes) en una muestra, esto no prueba la presencia de un virus. Un mejor diseño de cebadores tendría cebadores terminales en ambos extremos del genoma viral. Esto se debe a que se cubriría todo el genoma viral y tres señales positivas pueden discriminar mejor entre un virus completo (y por lo tanto potencialmente infeccioso) y genomas virales fragmentados (sin potencia infecciosa). Los científicos del equipo de Borger señalan: » Estas seis posiciones no especificadas podrían fácilmente resultar en el diseño de varias secuencias alternativas de cebadores que no se relacionan con el SARS-CoV-2... la confusa descripción no específica en el documento de Corman-Drosten no es adecuada como protocolo operativo estándar. Estas posiciones no especificadas deberían haber sido diseñadas de manera inequívoca». Añaden de manera general que «la RT-PCR no se recomienda para el diagnóstico primario de la infección. Por eso la prueba RT-PCR utilizada en la rutina clínica para la detección de COVID-19 no está indicada para el diagnóstico de COVID-19 sobre una base regulatoria».

Ciclos de amplificación. Pero sin duda lo más llamativo del protocolo Drosten es que no expuso en ningún momento de qué manera se determinan los resultados (positivo o negativo) resultantes tras las amplificaciones. El informe de Borger señala: «Estos tipos de pruebas de diagnóstico virológico deben basarse en un SOP (Protocolo Operativo Estándar) incluyendo un número validado y fijo de ciclos de PCR (valor Ct) después de los cuales una muestra se considera positiva o negativa. El máximo valor Ct razonablemente fiable es de 30 ciclos. Por encima de un Ct de 35 ciclos, se debe esperar un número rápidamente creciente de falsos positivos... los estudios científicos demuestran que sólo se detectan virus no infecciosos (muertos) con valores de Ct de 35”. Es un error significativo que el documento de Corman-Drosten no mencione el valor máximo de Ct con el que una muestra puede considerarse inequívocamente como un resultado de prueba positivo o negativo. Este importante límite de umbral del ciclo tampoco se especifica en ninguna de las comunicaciones de seguimiento realizadas hasta la fecha». Sin embargo, las recomendaciones de la OMS y del propio Drosten iban en el sentido de aplicar un Ct de 45 ciclos y, según se informa, actualmente los funcionarios de salud alemanes siguen aplicándolos. No es de extrañar el aumento significativo del número de pruebas al comienzo de la temporada de gripe invernal, y concluyen que «un resultado analítico con un valor Ct de 45 no tiene absolutamente ningún sentido desde el punto de vista científico y de diagnóstico».

Ausencia de validación. El trabajo del equipo Drosten-Corman basa la metodología de su producto en el uso de secuencias in silico (teóricas), suministradas por un laboratorio de China, porque en ese momento no se disponía de material de control del SARS-CoV-2 infeccioso («vivo») o inactivado ni de ARN genómico aislado del virus. Hasta la fecha, los autores no han realizado ninguna validación basada en virus aislados del SARS-CoV-2 o en el ARN completo del mismo. Los productos de la PCR amplificada deben ser validados ya sea presentando los productos en un gel con un transcriptor de ADN, o por secuenciación directa del ADN. «El hecho de que estos productos de la PCR no hayan sido validados a nivel molecular es otro error llamativo del protocolo, haciendo que cualquier prueba basada en él sea inútil como herramienta específica de diagnóstico para identificar el virus del SARS-CoV-2».

La Revisión externa por pares del equipo de Borger resulta tan concluyente que ha servido como base sustentatoria de la demanda formulada por el abogado Reiner Fuellmich. Presentada bajo la figura prejudicial del «cese y desista», la acción se encamina a la defensa de los intereses de un empresario hostelero (Nils Roth) quien, según el texto de la demanda, «ha sufrido y sigue sufriendo un daño significativo como resultado de las medidas sumamente desproporcionadas impuestas para contener la pandemia de COVID-19 sin un fundamento basado en pruebas». La comisión de un acto doloso contra el Sr Roth se fundamenta para Fuellmich en el hecho de que Drosten intervino de manera significativa y decisiva en las deliberaciones políticas, declaró hechos que sabía que eran falsos y perseveró en ellos, y, también intencionalmente, ocultó y continúa ocultando hechos significativos. Esta demanda, que solicita a Drosten una rectificación de todo su actuar y una compensación económica en favor del cliente afectado, obligará por lo tanto al acusado a refutar el trabajo del equipo de Borger y por lo tanto a demostrar – por fin, devolviendo la carga de la prueba al lugar que le corresponde en cualquier proceso científico – que la RT-PCR para COVID-19 formulada por Drosten y avalada por la OMS es válida para detección y diagnosis de la nueva enfermedad.



Attorney
Dr. Reiner Fuellmich
LL.M. (UCLA) - attorney at law
Authorized to represent at all courts in the US-federal state of California
Senderstraße 37
37077 Göttingen
Tel.: +49 (0) 551-20 91 20
Fax: +49 (0) 551-20 91 2144
E-Mail: info@fuellmich.com
www.fuellmich.com

Charité – Universitätsmedizin Berlin Institut für Virologie
Prof. Dr. Christian Drosten
Chariteplatz 1
10117 Berlin

!!! Urgent, strict time limit !!!

via fax beforehand 030 450 518911; date: 15.12.2020

Green Mango GmbH, represented by Nils Roth v. Prof Dr. Christian Drosten

Dear Professor Drosten,

We hereby give notice that Green Mango GmbH, Bülowstrasse 56, 10783 Berlin, represented by its managing director, Mr. Nils Roth, has commissioned us to represent its interests on the basis of the enclosed power of attorney. Our client has suffered and continues to suffer significant harm as a result of the grossly disproportionate measures imposed to contain the COVID-19 pandemic without an evidence-based foundation.

You are personally responsible for this harm because, as one of the individuals who intervened significantly and decisively in the policy deliberations, you stated facts which you knew to be false and still continue to do so, and, also intentionally, you concealed, and continue to conceal significant facts. In the name of and on behalf of our client, we claim that you should rectify your erroneous contribution to policy advice in connection with the COVID-19 crisis and compensate our client for the harm he has already suffered.

Texto que encabeza el «cese y desista» contra Drosten formulado por el abogado R. Fuellmich

4. El «caso Drosten» adentro del caso del fraude de las PCR

Y sin embargo, el cuestionamiento científico radical que supone el Informe Borger y la demanda de Fuellmich no son los únicos problemas a los que se enfrenta el profesor Dr. Christian Drosten hoy en día. La guinda sobre el escandaloso pastel: ¿es el Dr. Drosten, formulador de la prueba reina en la detección de Covid19 y principal asesor de Merkel para la crisis sanitaria, médico? Drosten y otros funcionarios de la Universidad Goethe de Frankfurt, donde afirma haber recibido su doctorado en medicina en 2003, están siendo acusados de fraude en la titulación. Según el Dr. Markus Kühbacher, especialista en la investigación de fraudes científicos como el plagio de tesis, la tesis doctoral del Dr. Drosten, como toda tesis, por ley debería haber sido depositada en una fecha determinada ante las autoridades académicas de su Universidad, quienes a continuación firman un formulario legal, «Revisionsschein», verificado con firma, sello de la Universidad y fecha, con el título de la tesis y el autor, para ser enviado al archivo de la Universidad en tres copias originales de la tesis. Kühbacher acusa a la Universidad de Goethe de encubrimiento al afirmar, falsamente, que la «Revisionsschein» de Drosten, estaba archivada. El portavoz de la Universidad se vio obligado a admitir que no estaba archivada, o al menos no era localizable por ellos. Además, de las tres copias de archivo obligatorias de su tesis doctoral, muy relevantes dada la importancia global del papel de Drosten en la dirección política de la gestión de la Covid19 en Alemania, en Europa y en el Mundo, dos copias han «desaparecido», y la única copia restante habría sido «dañada por el agua». Kühbacher afirma que es probable que Drosten se enfrente ahora a cargos judiciales por tener un título de doctorado fraudulento.

5. La OMS forzada a cuestionar la fiabilidad de la PCR

La Organización Mundial de la Salud emitió una nota de orientación el 14 de diciembre, en la que advertía que los umbrales de ciclo alto en las pruebas de PCR darán lugar a falsos positivos. El texto señala literalmente que «*conviene que los usuarios de reactivos de la prueba RT-PCR lean atentamente las instrucciones de uso a fin de determinar si es necesario efectuar ajustes manuales del umbral de positividad de la PCR con el fin de tener en cuenta el ruido de fondo que puede llevar a que una muestra con un valor alto de ciclo umbral (Ct) se interprete como un valor positivo*«.

Las preguntas que aquí podemos hacernos van en el sentido de lo señalado en el informe Borger contra el Protocolo Drosten para la RT-PCR: ¿ Cómo es posible que este test fuera validado por todas las autoridades de control (OMS y agencias estatales de salud) sin especificar con absoluta claridad el protocolo de uso, y específicamente el rango de amplificaciones mínimas y máximas necesarias para poder obtener resultados mínimamente confiables? ¿Por qué si la OMS conviene en señalar que el sólo positivo en RT-PCR no puede servir como diagnóstico en ningún caso (independientemente de los ciclos de amplificación aplicados en la prueba) y que es imprescindible contar con información clínica (síntomas) pero también con pruebas de validación que descarten «el ruido» presente en toda prueba de esta características (información genética no correspondiente a virus activos de ningún tipo), se está permitiendo que a nivel global sirvan sus realización no protocolizada como prueba diagnóstica mayoritaria, sino exclusiva? Por último, ¿habiendo estado esta información disponible desde al menos el mes de abril con advertencias múltiples por parte de diversos científicos, por qué lo están reportando ahora?

A pesar de los circunloquios empleados, la nota informativa de la OMS tiene todo el sentido y el aspecto de un tardío descargo de responsabilidad institucional por lo que pueda suceder con el crédito del organismo regulador de la salud global en el caso de que una investigación sistemática y a profundidad de toda la historia del testeo covídico confirmara lo que gran parte de la comunidad científica independiente lleva meses señalando y que coincide con el propio criterio de Kary Mullis, Nobel de Medicina e inventor de la PCR cuando comentaba que su test no debería en ningún caso utilizarse para diagnosis vírica ni para cuantificación de la carga viral, y que a nivel de la detección cualitativa funcionaba tan bien que cualquier usuario podría encontrar cualquier cosa que quiera encontrar en la muestra analizada.

https://abrelosojos.xyz/cuestiones-importantes/el-fraude-de-las-pcr-al-descubierto-3/

El test PCR va a los tribunales: en Portugal, pero también en Alemania y muchos otros países

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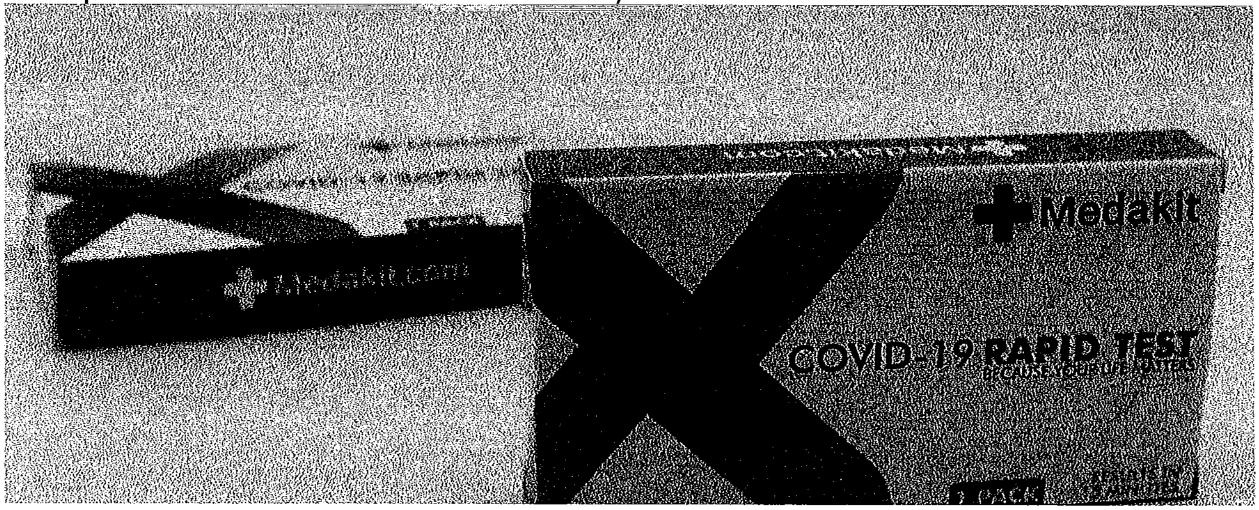

Demanda presentada en Berlín - infecciones no detectables.

Traducción gratuita del comunicado de prensa proporcionado por el abogado Reiner Fuellmich por correo electrónico. [1]

El test de PCR pende como una espada de Damocles sobre millones de alemanes desde hace meses. Dependiendo del resultado, existe el riesgo de interrupciones masivas en la vida diaria.

Este test ha llegado a los tribunales: se ha presentado una demanda ante el Tribunal Regional de Berlín.

El argumento principal: el test no es apto ni destinado a detectar una infección. Y eso haría que la cadena: test positivo - infectado - contagioso - peligro - este esquema es erróneo.

Primera etapa: la denuncia por difamación

En general, la denuncia de 54 páginas trata de la demanda por difamación contra el sitio web "Volksverpetzer". Este último, como "verificadores de hechos", ha insultado a las personas que criticaban las medidas contra el coronavirus y las difamaba como mentirosas, idiotas y extremistas de derecha.

El conocido especialista en pulmones, el Dr. Wolfgang Wodarg, antiguo jefe de un servicio de salud y miembro del Bundestag y del Consejo de Europa, está concernido. Recordemos

Que con la gripe porcina expuso las maquinaciones de la industria farmacéutica en 2010, y probablemente salvó a un sinnúmero de personas del daño. Desafortunadamente, cientos de niños que fueron vacunados a pesar de su advertencia sufren ahora de narcolepsia [2].

A principios de 2020, el Dr. Wodarg reconoció preocupantes paralelismos entre lo que pasó entonces y el Covid19 de hoy.

Estrategia global de los abogados alemanes

Esta acción de difamación es sólo una parte de una estrategia más amplia: se trata esencialmente de **exponer el uso incorrecto y abusivo del test de PCR.**

"queremos lograr dos objetivos", explicó el abogado de Göttingen, Dr. Reiner Füllmich, en cuyo despacho se redactó la denuncia sobre la base de los trabajos preliminares del Comité Covid19 en Berlín. El enlace es Wodarg, que también criticó los tests. [3]

"El test de PCR inadecuado es la piedra angular de toda la debacle causada por el coronavirus. Hay que romper esta piedra para que todo el castillo de naipes se derrumbe por fin", dijo Füllmich, explicando el verdadero propósito del juicio.

"El test de PCR no es adecuadao para determinar una infección" - esta es la conclusión unánime de varios científicos de la práctica clínica y la investigación diaria.

En julio, un grupo de abogados formado por Viviane Fischer, el Dr. Justus Hoffmann, Antonia Fischer y el Dr. Fuellmich fundaron en Berlín el "Comité de Investigación sobre la Gestión de Covid", y posteriormente invitaron a toda una armada de expertos de diversos campos especializados para averiguar los antecedentes de la crisis. El test de PCR fue discutido una y otra vez.

Los expertos confirmaron que test de PCR no es [nd1] t adecuado para el diagnóstico de Covid19. Este juicio crítico es confirmado por el CDC - la más alta autoridad sanitaria americana. El test PCR busca extractos del virus.

El CDC declaró: "La detección del ARN viral puede no indicar la presencia de un virus infeccioso o que el COVID-19 sea el agente causante de los síntomas clínicos".

El organismo llega a la conclusión, de que lo más probable es que una gran proporción de las decisiones difíciles, se basen en resultados de tests incorrectos".

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Incluso algunos miembros de la industria farmacéutica admiten el engaño. El Dr. Mike Yeadon, ex director y jefe científico del gigante farmacéutico Pfizer, habría declarado: "Este test es fatalmente defectuoso y debe ser retirado inmediatamente".

"Los test son alrededor de un 90% de falsos positivos. Serían "utilizadossólo para crear miedo".

Una evaluación similar procede del Canadá: el profesor de medicina Roger Hodgkinson declaró recientemente en una audiencia parlamentaria celebrada en Ottawa: "Quiero subrayar que participo activamente en la industria de los tests de COVID y que los resultados positivos de los tests no significan una infección clínica. Sólo crea histeria pública. »

El riesgo de que los menores de 65 años mueran a causa del COVID-19 es inferior a uno por cada 300.000 personas.

"Hay una histeria pública totalmente infundada llevada a cabo por los medios de comunicación y los políticos. Este es el mayor fraude jamás cometido contra un público confiado. "

El inventor del test PCR, el Premio Nobel Kary Mullis, que murió en 2019, había señalado repetidamente que el test PCR no puede diagnosticar una infección viral.

Incluso el virólogo jefe alemán Christian Drosten, el desarrollador del test de PCR para COVID-19, dijo en la "Wirtschaftswoche" en 2014 que el test de PCR también testearía positivamente a personas sanas y no contagiosas.

Sin embargo, desde mediados de enero de 2020, el test Drosten" ha sido la herramienta utilizada para evaluar a las "personas infectadas". Una contradicción flagrante.

Además, la denuncia indica claramente que durante el desarrollo del test Drosten PCR, que se ha vendido millones de veces en los EE.UU. sobre la base de la recomendación de la OMS, se cometieron errores flagrantes.

Estrategia más gobal

"Este juicio es sólo el primer paso hacia una estrategia aún más amplia", explicó el abogado Füllmich.

"Todas las medidas, desde el confinamiento -con devastadoras consecuencias económicas y psicológicas- hasta el declive de la educación, el arte y la cultura y la obligación de llevar una máscara, se basan en un test inadecuado.

Para el abogado, la crisis del coronavirus es una "pandemia de varios niveles" que constituye también una amenaza para la democracia y la libertad de expresión. Todo esto debe tratarse dentro del marco legal, y los responsables deben rendir cuentas.

Füllmich trabaja en estrecha colaboración con los otros abogados del Comité Corona Viviane Fischer, el Dr. Justus Hoffmann y Antonia Fischer, sus asesores médicos Prof. Dr. Ulrike Kämmerer y Dr. Wolfgang Wodarg y su asesor jurídico, Prof. Dr. Martin Schwab [4].

También existe una estrecha cooperación con los principales bufetes de abogados de los Estados Unidos -incluido el grupo de abogados encabezado por Robert F. Kennedy, Jr. y su Grupo de Defensa de la Salud Infantil- [5] y Canadá. Se espera que los primeros juicios comiencen en el Canadá en los próximos días.

Austria también está en los starting-blocks con un juicio con el mismo contenido. Un tribunal portugués levantó recientemente las medidas de cuarentena debido a la inadecuada del test de PCR, ya que se trataba de una "detención sin base factual" [6].

"Sobre la base de datos que hemos recopilado meticulosamente, cualquier abogado puede trabajar ahora aquí en Alemania y en el extranjero", dijo Füllmich.

Esto se aplica tanto a un ataque contra los tests de PCR como a los procedimientos judiciales contra otros medios de comunicación culpables de difamación a las personas que tienen una actitud crítica. El importe de la demanda judicial contra los "pérfidos" es de 250.000 euros. »

Este comunicado de prensa ha sido comentado en la prensa. Aquí hay algunos extractos de una entrevista al abogado Fuellmich en la prensa de habla alemana a principios de noviembre. Cabe señalar que la prensa francesa ha olvidado este aspecto tan importante de la lucha contra la manipulación de los pueblos mediante la práctica del test PCR a gran escala, sin que los laboratorios estén obligados a comunicar el número de ciclos de amplificación utilizados (e incluso la prohibición de transmitirlo a los pacientes).

Informar a los franceses sobre esta estafa que todavía les impide visitar las residencias de ancianos a permanecer aislados por las instrucciones de la ARS, de la que se esperan documentos legales que les permitan perseguir los llamados casos de contacto, por cerrar su negocio o abandonar a sus alumnos con el pretexto de un caso... Olvidamos que los casos no son en absoluto enfermos, y que los asintomáticos no son contagiosos, como confesó un representante de la OMS en junio, y esto fue confirmado recientemente en un artículo en la revista Nature.

La entrevista con el Dr. Reiner Füllmich tuvo lugar a principios de noviembre de 2020. Se publicó el 11 de noviembre de 2020 en el Fuldaer Zeitung impreso y también el 11 de noviembre de 2020 en una versión online ligeramente abreviada en fuldaerzeitung.de .

Extractos de esta entrevista en traducción "Crítica severa del confinamiento del covid19 : el abogado Reiner Füllmich ataca al virólogo Drosten y al jefe del RKI Wieler por Volker Nies [7]

Demanda colectiva en los Estados Unidos y demanda en los tribunales alemanes: el abogado de Göttingen, Dr. Reiner Füllmich (62 años), reclama una indemnización por daños y perjuicios a las empresas que han sufrido pérdidas debido al confinamiento relacionado con el covid.

Sr. Füllmich, usted representa a las empresas que han sufrido pérdidas debido a las exigencias de la crisis de Covid19 . ¿A quién persiguen usted y su equipo?

"Acusamos a los que dicen que el test PCR permite diagnosticar infecciones. Son sobre todo el virólogo Prof. Dr. Christian Drosten y Lothar Wieler, presidente del Instituto Robert Koch (RKI)".

"La acusación también está dirigida a los políticos que se apoyaron en los consejos de Drosten y Wieler. En el tribunal, preguntaremos por qué los políticos no escucharon también a otros expertos - tales como el ganador del Premio Nobel y profesor de Stanford John Ioannidis - que dicen que el virus es mucho menos peligroso de lo que afirman Drosten y el RKI. Calculó que el 0,14% de los pacientes afectados por la corona mueren. Esto significa que el coronavirus no es más peligroso que la gripe."

Las restricciones fueron ordenadas por el gobierno federal y estatal. ¿Por qué no los demandan?

"Queremos que los responsables, tanto del derecho civil como del penal, sean responsables en todos los casos. Empezamos donde estamos seguros de que tendremos éxito.

¿De qué está acusando a los expertos médicos?

"Si podemos probar que el Sr. Drosten y el Sr. Wieler en el tribunal mintieron deliberadamente, entonces hay un daño inmoral intencional según el artículo 826 BGB. Cuando se tomen las pruebas, los políticos también tendrán que responder, por supuesto".

Pregunta del periodista: Incluso si los consejos de Drosten y Wieler fueron erróneos, no son responsables del confinamiento.

"La política de confinamiento del Consejo de Drosten y Wieler es familiar. Ambos han hecho dos falsas declaraciones: dicen que si hay una infección asintomática - personas sin signos de enfermedad - podrían propagar el virus - y la infección puede ser detectada por los tests de PCR.

Los que difunden estas declaraciones falsas son responsables de ellas. Estamos en el tribunal probando que los tests de PCR no son apropiados para detectar la infección. »

Pregunta: El Instituto Robert Koch explica que la precisión del test de PCR es cercana al 100% si se realiza y evalúa correctamente.

Respuesta de R F: "Pero se trata del uso correcto. En el proceso del test de PCR, las trazas del genoma del virus se reproducen - en numerosos ciclos. En Alemania, todas los tests se ajustan, por supuesto, a valores elevados sobre un gran número de ciclos a fin de producir el mayor número posible de resultados positivos.

Sin embargo, un resultado positivo no significa que la persona afectada siga siendo contagiosa. Incluso los componentes genéticos de una gripe anterior pueden llevar a un resultado positivo."

P: El problema es el alto número de ciclos en el análisis?

R: "Entre otras cosas. El "New York Times" informa que la mayoría de los verdaderos resultados "falsos positivos" de PCR en los EE.UU. se basan en valores de ciclo muy altos. Existe cierta discusión sobre el rechazo general de los tests con más de 30 ciclos. El Departamento de Salud de Frankfurt está discutiendo ahora correctamente con el objetivo de ignorar todo por encima de los 25 ciclos."

¿Qué significa?

"Si el peligro del coronavirus es del 0,14%, es decir, al nivel de a gripe, y que los tests de PCR son en su mayoría falsos positivos, entonces el covid se ha transformado en una enfermedad muy peligrosa, lo cual no es la verdad.

Los tests de PCR son obviamente sólo una herramienta de pánico.

P: De nuevo: RKI dice que el test de PCR es extremadamente preciso cuando se hace correctamente.

"Entonces, ¿por qué no hacer los tests correctamente? ¿Entonces por qué Drosten, contra su propio juicio, está haciendo 45 ciclos? ¿Por qué, en contra del buen juicio, sólo una secuencia de genes se examina normalmente, y no seis, como han sugerido los chinos? Su método es mucho más preciso, pero es obviamente el objetivo en el mundo occidental producir tantos positivos pero falsos positivos como sea posible. Esto es una pandemia de tests."

P: Si los resultados positivos son en su mayoría falsos y el Coronavirus es tan peligroso como la gripe, ¿cómo se producen las muchas muertes - en Italia, España, EE.UU.?

"Aquí en Alemania no hay exceso de muertes de un año a otro. Esto también se debe al buen sistema de salud. En lo que respecta a los países extranjeros, la cuestión de la causalidad no debe simplificarse en absoluto.

Los abusos en el sistema de salud, los tratamientos médicos excesivos prescritos por miedo [8] y la población particularmente anciana de Italia: no se puede atribuir todo al peligro de un virus sin examinar las circunstancias con más detalle.

Pero se necesitaban fotos de pánico para mantener a la población en estado de shock y evitar a cualquiera que hiciera preguntas. Estas imágenes de horror vinieron de Bérgamo y Nueva York. Yo estaba en los Estados Unidos en ese momento. Estoy viviendo parcialmente allí y estoy autorizado a ejercer la abogacía en California".

¿Qué escuchaste allí?

"Mi amigo Wolfgang Wodarg, neumólogo y ex miembro del SPD del Parlamento alemán, tiene excelentes relaciones con los médicos de Nueva York. Algunos de los hospitales no estaban saturados en absoluto. [9]

El barco hospital de 1.000 camas enviado por los militares fue ocupado por 20 o 30 pacientes. Los hospitales afectados sufren cada año durante la temporada de gripe condiciones que el profesor Ioannidis describió como un "zona de teatro de guerra".

¿Cómo se produjo el alto número de muertes?

"Esta pregunta también tiene un contexto complejo. Debido al pánico, la gente acudió a los hospitales que de otra manera hubieran curado una pequeña infección en casa. En las salas, pueden haber sido infectados por los gérmenes del hospital, o pueden haber sido tratados en dosis excesivamente altas con agentes como la hidroxicloroquina, lo que puede haber aumentado la mortalidad, especialmente entre las personas de color, que a menudo sufren favismo y, por lo tanto, a menudo no pueden tolerar este medicamento.

Demasiados pacientes en Italia y Nueva York también han sido conectados a ventiladores en una etapa muy temprana, lo que puede ser fatal si se utiliza durante largos períodos de tiempo".

Pero no sólo ha habido muchas muertes por corona en la ciudad de Nueva York, sino en todo Estados Unidos - 240.000 hasta la fecha.

"330 millones de personas viven en los Estados Unidos, de las cuales alrededor de 7.300 mueren cada día, y esto no debe ser olvidado. De los 9,9 millones de personas que dieron positivo, alrededor del 0,2% murieron. Sin embargo, no se especifica aquí si murieron con o de covid. El número absoluto puede ser aterrador porque no está vinculado a otras muertes". [10]

¿Cuándo desea emprender acciones legales?

"Esta semana [11]. En los Estados Unidos, nuestro equipo trabaja con el abogado Robert F. Kennedy y su equipo. Bob Kennedy y yo nos conocimos por primera vez el 29 de agosto en Berlín, durante la manifestación contra las medidas de libertad en Alemania. ¡No hubo ni una palabra en los medios de comunicación cuando asistió un Kennedy! Los medios de comunicación informaron de 30.000 a 40.000 participantes, pero sabemos que se acercaba al millón."

¿Por qué está demandando en los Estados Unidos?

"En Estados Unidos, es mucho más fácil para un gran número de demandantes unir sus intereses en una demanda colectiva. No hay nada de eso en Alemania. El derecho a la prueba también es más justo en los EE.UU. cuando un consumidor demanda a una empresa poderosa.

¿Quiénes son los demandantes?

"Hay varias demandas colectivas. Los demandantes son principalmente empresarios estadounidenses que reclaman una indemnización por los daños sufridos. Durante el juicio, los demandantes argumentarán que hay millones de otras víctimas en todo el mundo. Pedirán a cualquiera que haya sido perjudicado por los tests y los confinamientos de la misma manera que sea admitido como demandante. También lo harán las empresas alemanas.

¿En qué tribunal de los EE.UU. desea demandar?

"Eso se decidirá en unas semanas. Pero primero, atacamos aquí en Alemania. Entonces los conclusiones de hechos también nos servirán en los Estados Unidos".

¿Dónde quiere emprender acciones en Alemania?

"Llevaremos a los responsables a los tribunales siempre que sea posible. La acuación permite que se presente una demanda por daños y perjuicios en los 200 tribunales alemanes, y eso va a suceder ahora. Representamos a empresas que dicen: "Ya basta, quiero saber, y los costos no importan".

¿Quiere pedir una indemnización al tribunal o tiene un objetivo político?

"Para mí, son las dos cosas: somos un grupo de más de 100 abogados. Originalmente, fuimos por daños y perjuicios. Pero la cuestión de la responsabilidad política es al menos igual de importante. »

En lo que respecta a la reclamación de daños y perjuicios, los procedimientos pueden durar años. Creemos que el rumbo se marcará desde el principio. Los tribunales examinarán las pruebas, con respecto a la pregunta: ¿de qué se tratan realmente estos tests de PCR?"

Suponemos que las cosas se moverán muy rápidamente si, por ejemplo, la conexión entre Christian Drosten y el empresario Olfert Landt sea discutida en público. »

El 2 de noviembre, el Tribunal de Distrito de Dortmund declaró inválidas las restricciones relacionadas con el covid porque se basaban en una orden del gobierno y no en una ley del Bundestag. ¿Cómo evalúa la sentencia contra la que el fiscal ya ha presentado una denuncia?

"Es un muy buen juicio. Está en línea con el Tribunal Constitucional de Austria y muchos tribunales americanos.

El gobierno puede tomar medidas de emergencia durante unos días.

Los plazos más prolongados, como hemos hecho y estamos haciendo en Alemania, sólo pueden ser decididos por el legislador. Hay un debate público, incluso más allá de las cuestiones inmediatas: ¿Qué hace una máscara y qué muestra un test de PCR?

El Bundestag quiere ahora aclarar la Ley de Protección contra la Infección: las decisiones que el estado puede ordenar deben ser determinadas con mayor precisión. Esto llega demasiado tarde, pero al menos ahora hay una discusión sobre lo que el estado puede y no puede ordenar. »

¿Realmente habrá una discusión abierta?

"Lo que es visible en la superficie no es exactamente la realidad. La segunda y tercera línea que los grupos políticos tienen una visión muy diferente. Hemos recibido señales de muchos miembros del Bundestag para la CDU / CSU y el SPD, incluyendo los Verdes, y por supuesto la AfD. Los diputados nos preguntan: ¿no hay alternativa del confinamiento ? Queda por ver cuán grande es el poder de la línea del frente. »

Aquí hay una telenovela muy interesante a seguir, si como lo espera R. Fuellmich, la denuncia de la estafa del los tests PCR sobre los cuales se basan los confinamientos y todas las medidas liberticidas, lleva al derrumbamiento del castillo de naipes. Informemos, porque el miedo debe desaparecer junto con los tests de PCR antes de que los gobernantes al servicio de la vacuna encuentren la forma de reemplazarlos para continuar su empresa del pánico.

Agradezcamos a los abogados de la comisión extraparlamentaria alemana que inició las investigaciones de los expertos internacionales con vistas a un Nuremberg del 19 y estimuló a los juristas internacionales a poner de relieve el engaño de los tests de Covid y las dramáticas medidas que resultaron y arruinaron la vida de miles, si no millones de personas en todo el mundo. Difundamos su trabajo para que el engaño ya no se oculte y para que los ciudadanos del mundo dejen de tener miedo y recuperen su fuerza para defender su libertad.

El video del abogado Reiner Fuellmich (enlaces en el primer artículo sobre el Nuremberg del covid video de YouTube) fue censurado por YouTube. Su discurso, en el que describe las medidas de Corona como un "crimen contra la humanidad", fue compartido 670.000 veces en YouTube - la versión en inglés aún más de un millón de veces.

[1]Wodarg, Dr Wolfgang./. Kreißel, Philip Queja del Dr. med.Wolfgang Wodarg, Wiesenweg 40, 24646 Tutor - Demandante - representado por: Rechtsanwälte

Dr. Fuellmich & Associates, Senderstrasse 37 en 37077 Göttingen contra Philip Kreißel, [dirección] - Demandado - por omisión, revocación y compensación monetaria. Importe provisional del litigio: 250.000 € Nos nombramos representantes del denunciante

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[2] En Francia, al menos 800 niños cuyas familias luchan por obtener una indemnización.

[3] Informamos en octubre del proyecto de Nuremberg 2 contra los responsables de esta falsa pandemia y de las trágicas consecuencias económicas y psíquicas sociales.

Nuremberg-Covid: los confinamientos eran innecesarios y siguen siéndolo (3)

Nuremberg-Covid: ¡un crimen contra la humanidad que debe ser juzgado!

Hacia el establecimiento de un Nuremberg del Covid – página web, ripostelaique.com

[4] Kurzbericht_Corona-Ausschuss_14-09-2020-1-4.pdf ver su información en su página web

[5] Pandemic Exposes How Science Is Suppressed for Political, Financial Gain • Children's Health Defense

[6] Las principales implicaciones de la jurisprudencia portuguesa sobre las pruebas de PCR (francesoir.fr)

[7] "WERKZEUG ZUR PANIKMACHE"

Harsche Kritik an Corona-Lockdown: Anwalt Reiner Fullmich greift Virologen Drosten und RKI-Chef Wieler an

[8] Piense en las muertes de Rivotril en las residencias de ancianos y en la aberrante prohibición del uso de hidroxicloroquina por parte del Ministro de Salud de Francia. La cifra de muertes de Rivotril sería de al menos 10.000 muertes y las muertes también están relacionadas con el abandono de la atención por enfermedades crónicas o no detectadas durante el confinamiento

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y las semanas siguientes (ataques cardíacos, accidentes cerebrovasculares, cánceres no tratados y no proyectado, etc.

¡No a las reconfinamientos mortales, incluso locales! - Doctora Nicole Delépine (nicoledelepine.fr)

[9] Recordemos que en Francia a pesar de los traslados teatrales por avión o TGV de algunos pacientes, las clínicas privadas estaban vacías en todo el país, prohibidas de la atención normal por el Plan Blanco impuesto por Edouard Philippe unos días antes del parto (reservado emergencias consideradas como tales por el ARS (agencia nacional de sanidad) y no por el cirujano o el paciente) y que no se les envió ningún paciente de covid19, salvo algunas excepciones. Cabe destacar que en la actualidad las clínicas privadas han vuelto a tener que cancelar muchos pacientes por orden de la ARS mientras la pseudo segunda ola ha terminado y los servicios hospitalarios no están saturados.

[10] Tenga en cuenta que los CDC de EE. UU. Admitieron recientemente que solo el 6% de los pacientes clasificados como muertos por covid realmente murieron por covid. En la propia Francia, el ministro admitió recientemente ante el Senado que era difícil determinar la proporción de muertes debidas al covid o asociadas al covid.

[11] De hecho, la denuncia fue presentada el 23 de noviembre de 2020 Klage des Dr. med. Wolfgang Wodarg, Wiesenweg 40, 24646 Warder - Kläger - Prozessbevollmächtigte: Rechtsanwälte Dr. Fuellmich & Associates, Senderstrasse 37 en 37077 Göttingen gegen Philip Kreißel, [Anschrift] - Bekufälagter - wegen Unterigeldung. Vorläufiger Streitwert: 250.000 € Wir bestellen uns zu Prozessbevollmächtigten des Klägers.

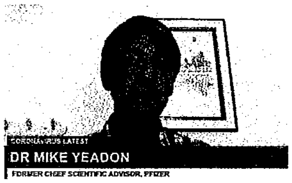
http://www.verdadypaciencia.com/2020/12/el-test-pcr-va-a-los-tribunales-en-portugal-pero-tambien-en-alemania-y-muchos-otros-paises.html

"Pandemic is Over" – Former Pfizer Chief Science Officer Says "Second Wave" Faked On False-Positive COVID Tests

TYLER DURDEN

This video provides one of the most erudite and informative looks at Covid-19 and the consequences of lockdowns. As AIER notes, **it was remarkable this week to watch as it appeared on YouTube and was forcibly taken down only 2 hours after posting.**

The copy below is hosted on LBRY, a blockchain video application. In a year of fantastic educational content, this is one of the best we've seen.


CORONAVIRUS LATEST
DR MIKE YEADON
FORMER CHIEF SCIENTIFIC ADVISOR, PFIZER

Consider the presenter's bio:

> ***Dr. Michael Yeadon is an Allergy & Respiratory Therapeutic Area expert with 23 years in the pharmaceutical industry. He trained as a biochemist and pharmacologist, obtaining his PhD from the University of Surrey (UK) in 1988.***
>
> *Dr. Yeadon then worked at the Wellcome Research Labs with Salvador Moncada with a research focus on airway hyper-responsiveness and effects of pollutants including ozone and working in drug discovery of 5-LO, COX, PAF, NO and lung inflammation. With colleagues, he was the first to detect exhaled NO in animals and later to induce NOS in lung via allergic triggers.*
>
> ***Joining Pfizer in 1995,*** *he was responsible for the growth and portfolio delivery of the Allergy & Respiratory pipeline within the company. He was responsible for target selection and the progress into humans of new molecules,* ***leading teams of up to 200 staff across all disciplines*** *and won an Achievement Award for productivity in 2008.*
>
> *Under his leadership the research unit invented oral and inhaled NCEs which delivered multiple positive clinical proofs of concept in asthma, allergic rhinitis and COPD. He led productive collaborations such as with Rigel Pharmaceuticals (SYK inhibitors) and was involved in the licensing of Spiriva and acquisition of the Meridica (inhaler device) company.*
>
> ***Dr. Yeadon has published over 40 original research articles*** *and now consults and partners with a number of biotechnology companies.* ***Before***

working with Apellis, Dr. Yeadon was VP and Chief Scientific Officer (Allergy & Respiratory Research) with Pfizer.

What likely triggered the Silicon Valley censor-mongers is the fact that a former Chief Science Officer for the pharmaceutical giant Pfizer says ***"there is no science to suggest a second wave should happen."*** The "Big Pharma" insider asserts that false positive results from inherently unreliable COVID tests are being used to manufacture a "second wave" based on "new cases."

As Ralph Lopez write at HubPages, **Yeadon warns that half or even "almost all" of tests for COVID are false positives.** Dr. Yeadon also argues that the threshold for herd immunity may be much lower than previously thought, and may have been reached in many countries already.

In an interview last week (see below) Dr. Yeadon was asked:

"we are basing a government policy, an economic policy, a civil liberties policy, in terms of limiting people to six people in a meeting…all based on, what may well be, completely fake data on this coronavirus?"

Dr. Yeadon answered with a simple "**yes**."

Even more significantly, even if all positives were to be correct, Dr. Yeadon said that given the "shape" of all important indicators in a worldwide pandemic, such as hospitalizations, ICU utilization, and deaths, "the pandemic is fundamentally over."

Yeadon said in the interview:

"Were it not for the test data that you get from the TV all the time, you would rightly conclude that the pandemic was over, as nothing much has happened. *Of course people go to the hospital, moving into the autumn flu season…but* ***there is no science to suggest a second wave should happen."***

In a paper published this month, which was co-authored by Yeadon and two of his colleagues, "How Likely is a Second Wave?", the scientists write:

"It has widely been observed that in all heavily infected countries in Europe and several of the US states likewise, that the shape of the daily deaths vs. time curves is similar to ours in the UK. ***Many of these curves are not just similar, but almost super imposable."***

In the data for UK, Sweden, the US, and the world, it can be seen that in all cases, deaths were on the rise in March through mid or late April, then began tapering off in a smooth slope which flattened around the end of June and continues to today. The case rates however, ***based on testing,*** rise and swing upwards and downwards wildly.

Media messaging in the US is already ramping up expectations of a "second wave."

The survival rate of COVID-19 has been upgraded since May to 99.8% of infections. This comes close to ordinary flu, the survival rate of which is 99.9%. Although COVID can have serious after-effects, so can flu or any respiratory illness. The present survival rate is far higher than initial grim guesses in March and April, cited by Dr. Anthony Fauci, of 94%, or 20 to 30 times deadlier. The

Infection Fatality Rate (IFR) value accepted by Yeadon *et al* in the paper is .26%. The survival rate of a disease is 100% minus the IFR.

Dr. Yeadon pointed out that the "novel" COVID-19 contagion is novel only in the sense that it is a new type of coronavirus. But, he said, there are presently four strains which circulate freely throughout the population, most often linked to the common cold.

In the scientific paper, Yeadon *et al* write:

> *"There are at least four well characterised family members (229E, NL63, OC43 and HKU1) which are endemic and cause some of the common colds we experience, especially in winter. They all have striking sequence similarity to the new coronavirus."*

The scientists argue that much of the population already has, if not antibodies to COVID, some level of **"T-cell" immunity from exposure to other related coronaviruses,** which have been circulating long before COVID-19.

The scientists write:

> *"A major component of our immune systems is the group of white blood cells called T-cells whose job it is to memorise a short piece of whatever virus we were infected with so the right cell types can multiply rapidly and protect us if we get a related infection. Responses to COVID-19 have been shown in dozens of blood samples taken from donors before the new virus arrived."*

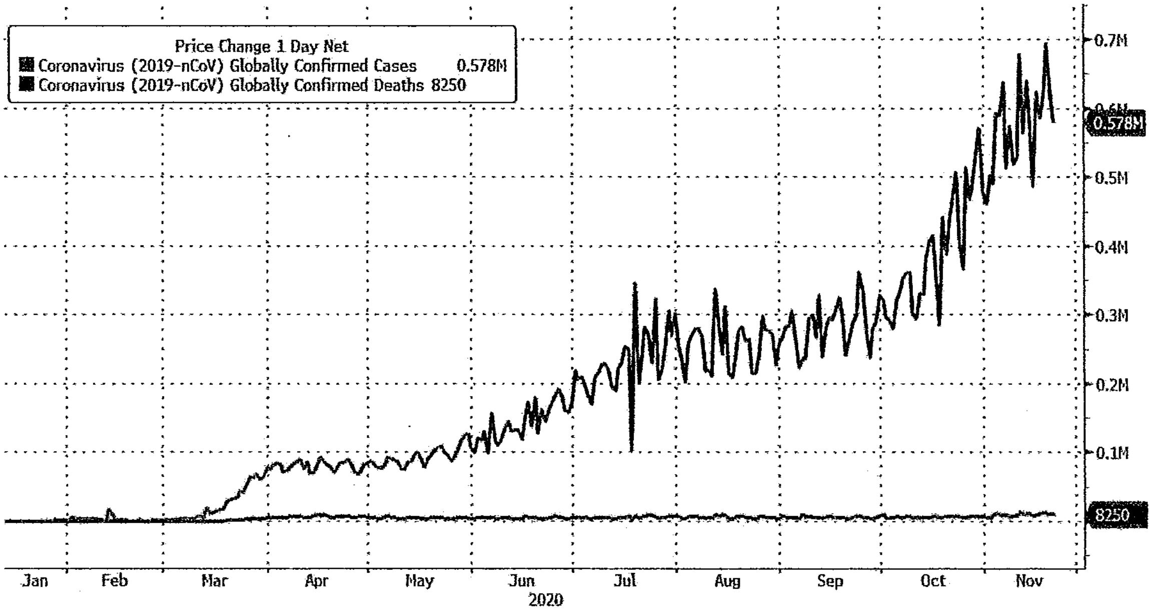
Introducing the idea that some prior immunity to COVID-19 already existed, the authors of "How Likely is a Second Wave?" write:

> ***"It is now established that at least 30% of our population already had immunological recognition of this new virus, before it even arrived…COVID-19 is new, but coronaviruses are not."***

They go on to say that, because of this prior resistance, **only 15-25% of a population being infected may be sufficient to reach herd immunity**:

> *"…epidemiological studies show that, with the extent of prior immunity that we can now reasonably assume to be the case, only 15-25% of the population being infected is sufficient to bring the spread of the virus to a halt…"*

In the US, accepting a death toll of 200,000, and a survival rate of 99.8%, this would mean for every person who has died, there would be about 400 people who had been infected, and lived. This would translate to around 80 million Americans, or 27% of the population. **This touches Yeadon's and his colleagues' threshold for herd immunity.**



Finally, the former Pfizer executive and scientist singles out one former colleague for withering rebuke for his role in the pandemic, Professor Neil Ferguson (pictured). Ferguson taught at Imperial College while Yeadon was affiliated. Ferguson's computer model provided the rationale for governments to launch draconian orders which turned free societies into virtual prisons overnight. Over what is now estimated by the CDC to be a 99.8% survival rate virus.

Dr. Yeadon said in the interview that "no serious scientist gives any validity" to Ferguson's model.

Speaking with thinly-veiled contempt for Ferguson, Dr. Yeadon took special pains to point out to his interviewer:

"It's important that you know most scientists don't accept that it [Ferguson's model] was even faintly right...but the government is still wedded to the model."

Yeadon joins other scientists in castigating governments for following Ferguson's model, the assumptions of which all worldwide lockdowns are based on. One of these scientists is Dr. Johan Giesecke, former chief scientist for the European Center for Disease Control and Prevention, who **called Ferguson's model "the most influential scientific paper" in memory, and also "one of the most wrong."**

It was Ferguson's model which held that "mitigation" measures were necessary, i.e. social distancing and business closures, in order to prevent, for example, over 2.2 million people dying from COVID in the US.

Ferguson predicted that Sweden would pay a terrible price for no lockdown, with 40,000 COVID deaths by May 1, and 100,000 by June. Sweden's death count is under 6,000. The Swedish government says this corresponds to a mild flu season. Although initially higher, Sweden now has a lower death rate per-capita than the US, which it achieved without the terrific economic damage still ongoing in the US. Sweden never closed restaurants, bars, sports, most schools, or movie theaters. The government never ordered people to wear masks.

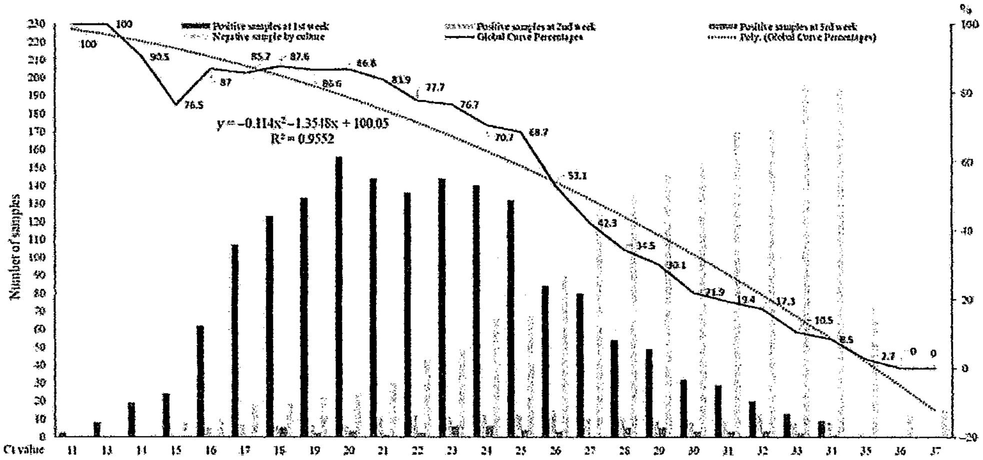
Dr. Yeadon speaks bitterly of the lives lost as a result of lockdown policies, and of the "saveable" countless lives which will be further lost, from important surgeries and other healthcare deferred, should lockdowns be reimposed.

Watch the full discussion below:

Yeadon's warnings are confirmed by a new study from the Infectious Diseases Society of America., summarized succinctly in the following twitter thread from al gato malo (@boriquagato)

Anyone still presuming that a Positive PCR test is showing a COVID case needs to read this very carefully:

- **even with 25 cycles of amplification, 70% of "positives" are not "cases." Virus cannot be cultured; it's dead.**
- by **35:** 97% non-clinical.
- the US runs at **40**, 32X the amplification of 35. ***(ER: France is using cycle thresholds of 35-40)***



Ct value	11	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37
Number of samples (N = 3790)	2	8	21	34	77	133	153	161	190	186	193	210	225	217	192	218	206	209	196	211	208	220	213	74	15	15
Total positive (n = 1941)	2	8	19	26	67	114	134	142	165	156	150	161	159	149	102	90	71	63	43	41	36	23	18	2	0	0
Week 1: number of positives (n = 1700)	2	8	19	24	62	107	123	133	156	144	136	144	140	132	84	80	54	49	32	29	20	13	9	0	0	0
(% by total positive)	(100)	(100)	(100)	(92.3)	(92.5)	(93.9)	(91.8)	(93.7)	(94.5)	(92.3)	(90.7)	(89.4)	(88.1)	(88.6)	(82.4)	(88.9)	(76.1)	(77.8)	(74.4)	(70.7)	(55.6)	(56.5)	(50.0)	(0)	(-)	(-)
Week 2: number of positives (n = 187)	0	0	0	2	5	7	6	7	6	11	12	11	13	13	15	10	12	9	8	9	13	8	8	2	0	0
(% by total positive)	(0)	(0)	(0)	(7.7)	(7.5)	(6.1)	(4.5)	(4.9)	(3.6)	(7.1)	(8.0)	(6.8)	(8.2)	(8.7)	(14.7)	(11.1)	(16.9)	(14.3)	(18.6)	(22.0)	(36.1)	(34.8)	(44.0)	(100)	(-)	(-)
Week 3: number of positives (n = 54)	0	0	0	0	0	0	5	2	3	1	2	6	6	4	3	0	5	5	3	3	3	2	1	0	0	0
(% by total positive)	(0)	(0)	(0)	(0)	(0)	(0)	(3.7)	(1.4)	(1.8)	(0.6)	(1.3)	(3.7)	(3.8)	(2.7)	(2.9)	(0)	(7.0)	(7.9)	(7.0)	(7.3)	(8.3)	(8.7)	(5.6)	(0)	(-)	(-)
Negative cultured (n = 1849)	0	0	2	8	10	19	19	22	25	30	43	49	66	68	90	128	135	146	153	170	172	197	195	72	15	15

Figure 1. Percentage of positive viral cultures of severe acute respiratory syndrome coronavirus 2 polymerase chain reaction–positive nasopharyngeal samples from coronavirus disease 2019 patients, according to Ct value (plain line). The dashed curve indicates the polynomial regression curve. Abbreviations: Ct, cycle threshold; Poly., polynomial.

A lot of people still seem to not understand what this means, so let's lay that out for a minute.

PCR tests look for RNA. There is too little in your swab, so they amplify it using a primer-based heating and annealing process.

Each cycle of this process doubles the material

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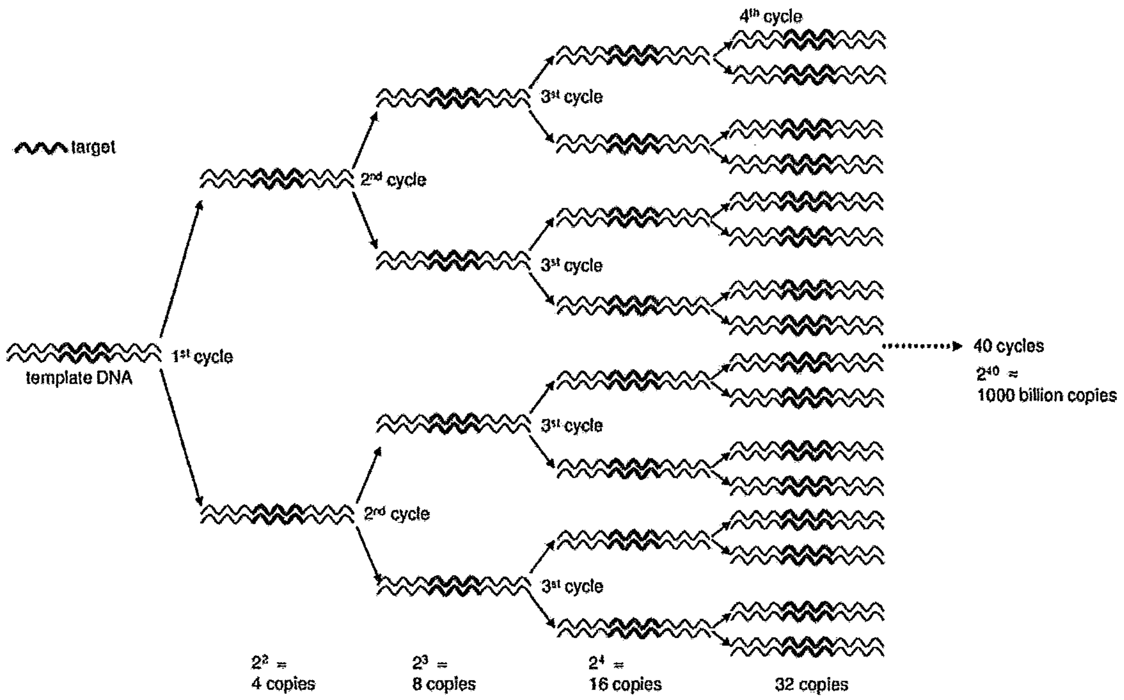

target
template DNA
1st cycle
2nd cycle
3rd cycle
4th cycle
40 cycles
2^{40} ≈
1000 billion copies
2^2 =
4 copies
2^3 =
8 copies
2^4 =
16 copies
32 copies

The US (and much of the world) is using a 40 Ct (cycle threshold). So, 40 doublings, 1 trillion X amplification.

This is absurdly high.

The way that we know this is by running this test, seeing the Ct to find the RNA, and then using the same sample to try to culture virus.

If you cannot culture the virus, then the virus is "dead." It's inert. If it cannot replicate, **it cannot infect you or others.** It's just traces of virus, remnants, fragments, etc.

PCR is not testing for disease, it's testing for a specific RNA pattern and this is the key pivot.

When you crank it up to 25, 70% of the positive results are not really "positives" in any clinical sense.

I hesitate to call it a "false positive" because it's really not. It did find RNA, but that RNA is not clinically relevant.

It cannot make you or anyone else sick

So let's call this a non-clinical positive (NCP).

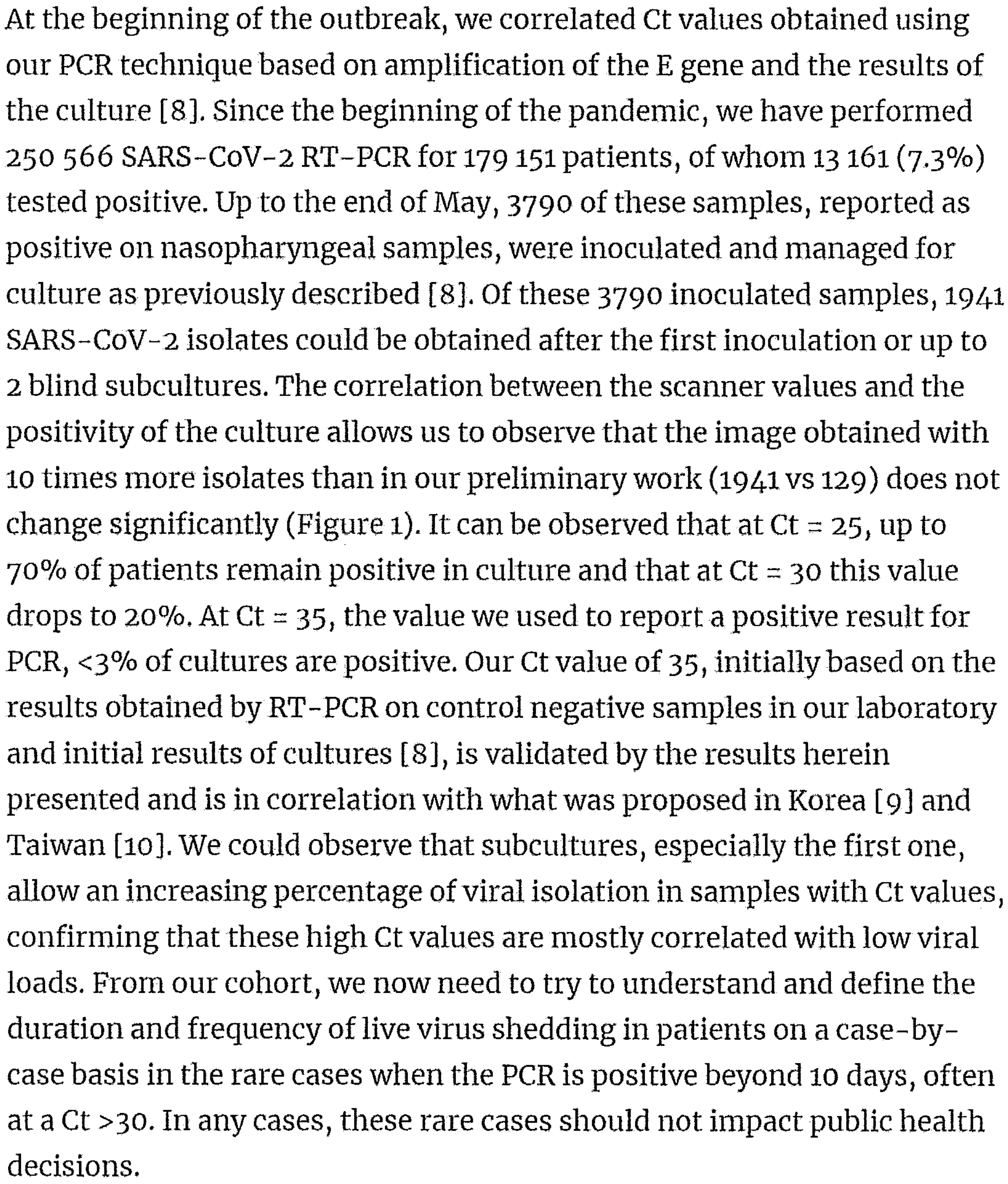
- if 70% of positives are NCP's at 25, imagine what 40 looks like. 35 is 1,000X as sensitive.
- this study found only 3% live at 35
- 40 Ct is 32X 35, 32,000X 25

No one can culture live virus past about 34 and we have known this since March. yet no one has adjusted these tests.

This is more very strong data refuting the idea that you can trust a PCR+ as a clinical indicator.

That is NOT what it's meant for. At all.

Using them to do real time epidemiology is absurd.



> At the beginning of the outbreak, we correlated Ct values obtained using our PCR technique based on amplification of the E gene and the results of the culture [8]. Since the beginning of the pandemic, we have performed 250 566 SARS-CoV-2 RT-PCR for 179 151 patients, of whom 13 161 (7.3%) tested positive. Up to the end of May, 3790 of these samples, reported as positive on nasopharyngeal samples, were inoculated and managed for culture as previously described [8]. Of these 3790 inoculated samples, 1941 SARS-CoV-2 isolates could be obtained after the first inoculation or up to 2 blind subcultures. The correlation between the scanner values and the positivity of the culture allows us to observe that the image obtained with 10 times more isolates than in our preliminary work (1941 vs 129) does not change significantly (Figure 1). It can be observed that at Ct = 25, up to 70% of patients remain positive in culture and that at Ct = 30 this value drops to 20%. At Ct = 35, the value we used to report a positive result for PCR, <3% of cultures are positive. Our Ct value of 35, initially based on the results obtained by RT-PCR on control negative samples in our laboratory and initial results of cultures [8], is validated by the results herein presented and is in correlation with what was proposed in Korea [9] and Taiwan [10]. We could observe that subcultures, especially the first one, allow an increasing percentage of viral isolation in samples with Ct values, confirming that these high Ct values are mostly correlated with low viral loads. From our cohort, we now need to try to understand and define the duration and frequency of live virus shedding in patients on a case-by-case basis in the rare cases when the PCR is positive beyond 10 days, often at a Ct >30. In any cases, these rare cases should not impact public health decisions.

The FDA would never do it, the drug companies doing vaccine trials would never do it… it's **because it's nonsense.**

And this same test is used for "hospitalizations" and "death with covid" (itself a weirdly over inclusive metric)

PCR testing is not the answer, it's the problem.

It's not how to get control of an epidemic, it's how to completely lose control of your data picture and wind up with gibberish and we have done this to ourselves before.

A quick word what this data does and does not mean.

Saying "a sample requiring 35 Ct to test + has a 3% real clinical positive rate" does not mean "97% of + tests run at 35 Ct are NCP's"

People seem to get confused on this, so let's explain:

Most tests are just amplified and run. They don't test every cycle as these academics do. That would make the test slow and expensive, so you just run 40 cycles then test.

Obviously, a real clinical positive (RCP) that would have been + at 20 is still + at 40.

But when you run the tests each cycle as the academics do, that test would already have dropped out.

So saying that only 3% at 35 are RCP really means that 3% of those samples not PCR + at 34 were PCR and RCP + at 35.

This lets us infer little about overall NCP/RCP rate.

So we cannot say "at 25 Ct, we have a 70 NCP rate." In fact, it's hard to say much of anything. It depends entirely on what the source material coming in looks like.

You cannot even compare like to like.

This is what i mean by "the data is gibberish"

Today at 40 Ct, 7% PCR positive rate could be 1% RCP prevalence when that same thing meant 6% RCP prev in april.

If there is lots more trace virus around, more people who have recovered and have fragments left over, etc, this test could be finding virus *you killed 4 months ago.*

So if we consider RCP rate/PCR+ rate, we would expect that number to drop sharply late in an epidemic because there is more dead virus around for PCR to find, but we have no idea what that ratio is or how it changes.

This spills over in to deaths, reported hospitalization, etc.

Testing is being made out to be like the high beams on a car, but when it's snowing like hell at night, that is the LAST thing you want. It is not illuminating our way, it's blinding us.

A bad inaccurate map is much worse than no map at all, and this is a world class bad map...

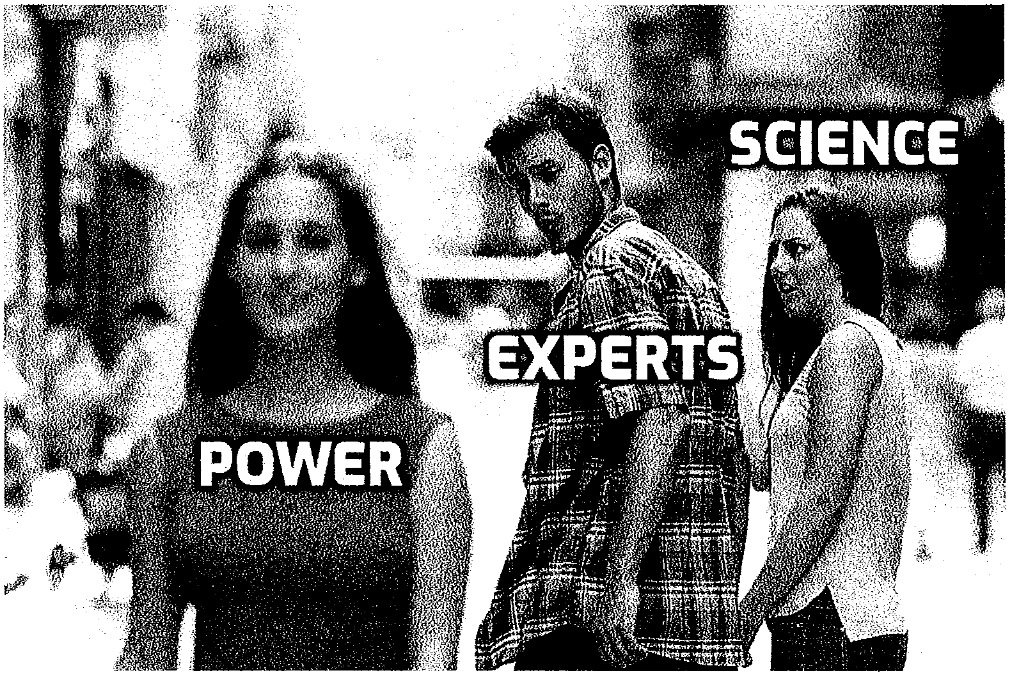
We're basing policy that is affecting billions of humans on data that is uninterpretable gibberish.

It's a deranged technocrat's wet dream, but for those of us along for the ride, it's a nightmare.

Testing is not the solution, it's the problem.

Any technocrat or scientist that does not know this by now is either unfit for their job or has decided that they just don't care and prefer power to morality.

This is, of course, precisely the kind of person who winds up running a gov't agency… oopsie.



The head of the NIH is not the best scientist, it's the best politician.

All this wild and reckless government policy has never been about the science.

It's politics and panic.

You can read the whole paper here:

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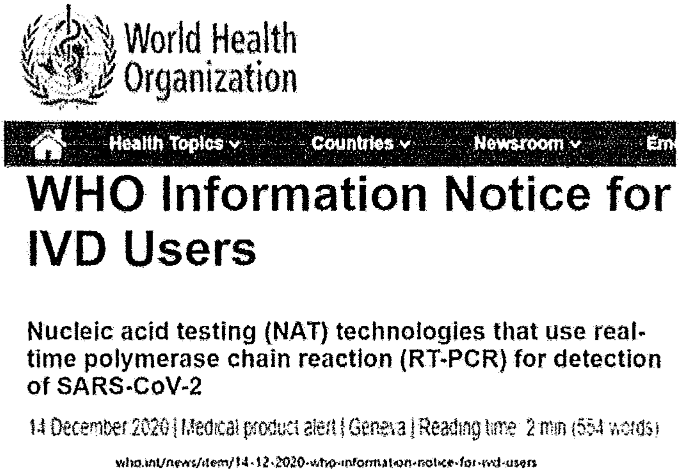
https://www.thelibertybeacon.com/pandemic-is-over-former-pfizer-chief-science-officer-says-second-wave-faked-on-false-positive-tests/

WHO Finally Admits COVID19 PCR Test Has A 'Problem'

Published on December 17, 2020

Written by John O'Sullivan



World Health Organization

WHO Information Notice for IVD Users

Nucleic acid testing (NAT) technologies that use real-time polymerase chain reaction (RT-PCR) for detection of SARS-CoV-2

14 December 2020 | Medical product alert | Geneva | Reading time 2 min (554 words)

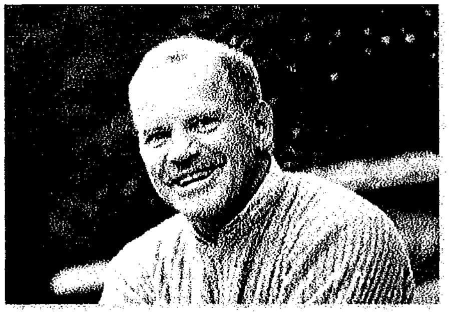
who.int/news/item/14-12-2020-who-information-notice-for-ivd-users

In a statement released on December 14, 2020 the World Health Organization finally owned up to what 100,000's of doctors and medical professionals have been saying for months: the PCR test used to diagnose COVID-19 is a hit and miss process with way too many false positives.

This WHO-admitted "Problem" comes in the wake of international lawsuits exposing the incompetence and malfeasance of public health officials and policymakers for reliance on a diagnostic test *not fit for purpose.*

This World Health Organization admission is that the crux of the "***problem***" is a wholly arbitrary cycling process which "*means that many cycles were required to detect virus. In some circumstances,* ***the distinction between background noise and actual presence of the target virus is difficult to ascertain.***" [emphasis added]

The UN body is now clearly looking to distance itself from the fatally flawed test as a growing number of lawsuits are processing through the courts exposing the insanity of relying on a test that even the inventor, Professor Kary B. Mullis said was ***never designed to diagnose diseases.*** [1]



Kary Mullis (1944-2019)

Professor Mullis was awarded the Nobel Prize in Chemistry in 1993. 'Coincidentally', Mullis died just before the pandemic started

We reported on November 22, 2020 that a landmark court case in Portugal had ruled that the polymerase chain reaction test (PCR) used worldwide to diagnose COVID-19 was not fit for purpose. Most importantly, the judges ruled that ***a single positive PCR test cannot be used as an effective diagnosis of infection.***

As Off-Guardian.org reported at the time:

"In their ruling, judges Margarida Ramos de Almeida and Ana Paramés referred to several scientific studies. Most notably this study by Jaafar et al., which found that – when running PCR tests with 35 cycles or more – the accuracy dropped to 3%, meaning up to 97% of positive results could be false positives.

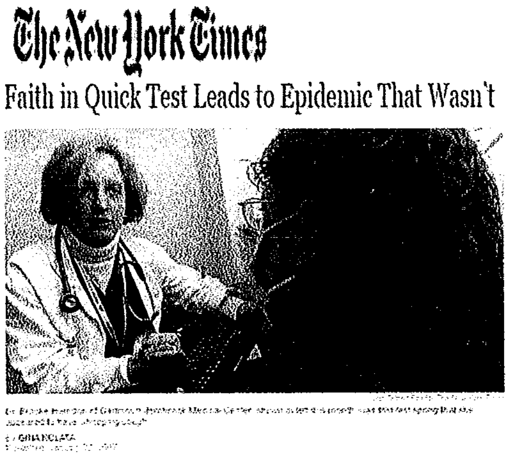
The ruling goes on to conclude that, based on the science they read, any PCR test using over 25 cycles is totally unreliable. Governments and private labs have been very tight-lipped about the exact number of cycles they run when PCR testing, but it is known to sometimes be as high as 45. Even fearmonger-in-chief Anthony Fauci has publicly stated anything over 35 is totally unusable."

You can read the complete ruling in the original Portuguese here, and translated into English here.

Among thousands of angry doctors arguing PCR tests should not be used is Dr. Pascal Sacré. He wrote that:

*"This misuse of RT-PCR technique is used as **a relentless and intentional strategy by some governments**, supported by scientific safety councils and by the dominant media, **to justify excessive measures** such as the violation of a large number of constitutional rights, the destruction of the economy with the bankruptcy of entire active sectors of society, the degradation of living conditions for a large number of ordinary citizens, under the pretext of a pandemic **based on a number of positive RT-PCR tests, and not on a real number of patients**."*

Clear and conclusive scientific evidence proves that these tests are not accurate and create a statistically significant percentage of false positives. **Positive results more likely indicate "ordinary respiratory diseases like the common cold."** [2]



The New York Times

Faith in Quick Test Leads to Epidemic That Wasn't

However, none of this is new information to science. These facts were known at least before 2007 after a *New York Times* report entitled, *"Faith in Quick Test Leads to Epidemic That Wasn't,"* (image, above) clearly showed how scientifically inaccurate PCR tests are, featuring many shocking statements from medical experts on the use of these tests, clearly laying out how they result in false positives and lead to ***dangerous exaggerations and false alarms***. [3]

In their 2007 story the New York Times cited a prescient quote from Dr. Elizabeth Talbot, deputy state epidemiologist for the New Hampshire Department of Health and Human Services, who said:

"One Of The Most Troubling Aspects Of The Pseudo-Epidemic Is That All The Decisions Seemed So Sensible At The Time."

Those who run our public institutions have allowed history to repeat itself. At the head of the line of incompetence and malfeasance is the UN itself. At the media briefing on COVID-19 on March 16, 2020, the WHO Director General Dr Tedros Adhanom Ghebreyesus (photo, below) said:

"We Have A Simple Message For All Countries: Test, Test, Test."

This insanity of testing anyone and everyone, even without symptoms has been an unmitigated global public health scandal and must be stopped. All officials in high places complicit in this crime must be prosecuted.

About the author: John O'Sullivan *John is CEO and co-founder (with Dr Tim Ball) of Principia Scientific International (PSI). John is a seasoned science writer and legal analyst who assisted Dr Ball in defeating world leading climate expert, Michael 'hockey stick' Mann in the 'science trial of the century'. O'Sullivan is credited as the visionary who formed the original 'Slayers' group of scientists in 2010 who then collaborated in creating the world's first full-volume debunk of the greenhouse gas theory plus their new follow-up book.*

[1] Kary Mullis : « Le test PCR ne permet pas de savoir si vous êtes malade », vidéo accessible sur YouTube, 9 octobre 2020.

[2] David DeGraw, Torsten Engelbrecht and Konstantin Demeter, https://www.globalresearch.ca/national-security-alert-covid-tests-scientifically-fraudulent-epidemic-false-positives/5720271

[3] New York Times,*'Faith in Quick Test Leads to Epidemic That Wasn't,'* Gina Kolota, Published: January 22, 2007

Reference: https://principia-scientific.com/who-finally-admits-covid19-pcr-test-has-a-problem/

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WHO Information Notice for IVD Users

Nucleic acid testing (NAT) technologies that use real-time polymerase chain reaction (RT-PCR) for detection of SARS-CoV-2

14 December 2020

Medical product alert

Geneva

Reading time: 2 min (554 words)

Product type: Nucleic acid testing (NAT) technologies that use real-time polymerase chain reaction (RT-PCR) for detection of SARS-CoV-2

Date: 7 December 2020

WHO-identifier: 2020/5, version 1

Purpose of this notice: To ensure users of certain nucleic acid testing (NAT) technologies are aware of certain aspects of the instructions for use (IFU) for all products.

Description of the problem: WHO has received user feedback on an elevated risk for false SARS-CoV-2 results when testing specimens using RT-PCR reagents on open systems.

As with any diagnostic procedure, the positive and negative predictive values for the product in a given testing population are important to note. As the positivity rate for SARS-CoV-2 decreases, the positive predictive value also decreases. This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as positivity rate decreases, irrespective of the assay specificity. Therefore, healthcare providers are encouraged to take into consideration testing results along with clinical signs and symptoms, confirmed status of any contacts, etc.

Users of RT-PCR reagents should read the IFU carefully to determine if manual adjustment of the PCR positivity threshold is necessary to account for any background noise which may lead to a specimen with a high cycle threshold (Ct) value result being interpreted as a positive result. The design principle of RT-PCR means that for patients with high levels of circulating virus (viral load), relatively few cycles will be needed to detect virus and so the Ct value will be low. Conversely, when specimens return a high Ct value, it means that many cycles were required to detect virus. In some circumstances, the distinction between background noise and actual presence of the target virus is difficult to ascertain. Thus, the IFU will state how to interpret specimens at or near the limit for PCR positivity. In some cases, the IFU will state that the cut-off should be manually adjusted to ensure that

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specimens with high Ct values are not incorrectly assigned SARS-CoV-2 detected due to background noise.

Manufacturers regularly review the design of their product, including labelling and IFU based on customer feedback. In the early phases of the COVID-19 pandemic, in vitro diagnostics (IVDs) were rapidly developed, validated and verified, and then rolled out. Therefore, it is not unexpected that IVDs may require refinement based on user feedback after their introduction at scale. Users should verify the version of the IFU with each consignment they receive to see if any changes have been made to the IFU.

Advice on action to be taken by users:

1. Please read carefully the IFU in its entirety.
2. Contact your local representative if there is any aspect of the IFU that is unclear to you.
3. Check the IFU for each incoming consignment to detect any changes to the IFU.
4. Consider any positive result (SARS-CoV-2 detected) or negative results (SARS-CoV-2 not detected) in combination with specimen type, clinical observations, patient history, and epidemiological information.
5. Provide the Ct value in the report to the requesting healthcare provider.

Transmission of this WHO Information Notice for Users:

Please disseminate this notice to all those who need to be aware within your organization or to any organization where the potentially affected product has been deployed and used.

Contact person for further information:

Anita SANDS, Regulation and Prequalification, World Health Organization, e-mail: sandsa@who.int

https://web.archive.org/web/20201215013928/https://www.who.int/news/item/14-12-2020-who-information-notice-for-ivd-users

miércoles, 31 de marzo de 2021 Telegram Facebook Twitter MeWe Gab WeChat ✉ ¡SUSCRIBIRSE AL INFORME SEMANAL!

CIENCIA Y TECNOLOGÍA SUCESOS INTERNET PARANORMAL

Difusión de noticias alternativas

INICIO TODO DESTACADO ARTÍCULOS SALUD POLÍTICA ECONOMÍA

CIENCIA Y TECNOLOGÍA SUCESOS INTERNET PARANORMAL

Inicio > Sucesos

Un tribunal de Viena dictamina que la PCR no es suficiente como prueba de infección y desmantela las medidas COVID del gobierno al igual que la prohibición de manifestaciones en Austria

31 de marzo de 2021 en **Sucesos, Destacado** 👍 0 👎 0 💬 0

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INICIO **TODO** **DESTACADO** **ARTÍCULOS** **SALUD** **POLÍTICA** **ECONOMÍA**
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Un fallo del Tribunal Administrativo de Viena sobre la prohibición de reuniones equivale a romper la política COVID del gobierno actual. Las definiciones de enfermedad del ministro de salud son incorrectas y una prueba de PCR para el diagnóstico de COVID-19 no sería adecuada según el fallo. Tampoco es la primera vez que la controvertida prueba llega a unos tribunales.

Publicidad:

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El Departamento de Policía del Estado de Viena había prohibido las manifestaciones contra las medidas COVID del gobierno anunciadas por el Partido de la Libertad de Austria (FPÖ) para el 30 y 31 de enero. Como justificación, el departamento de policía obtuvo una declaración del servicio de salud de la ciudad de Viena y una nota en el expediente de la Oficina Estatal para la Protección de la Constitución y el Terrorismo (LVK). En él, la autoridad llamó la atención sobre el mayor riesgo que representa la mutación británica.

En protesta, el FPÖ presentó una denuncia en el Tribunal Administrativo de Viena, y ganó. El

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Publicidad:

Sin embargo, la decisión carece de una justificación sostenible para una prohibición por otras razones. Según *Der Standard,* el juez «formalmente» «recoge» la opinión del Servicio de Salud de Viena.

Por un lado, se critica que términos médicos como «número de casos, resultados de las pruebas, historial del caso» y «número de infecciones» se confundan en el comunicado. Eso no haría justicia a una evaluación científica de la situación epidémica.

El tribunal tampoco está satisfecho con la referencia a la Comisión Corona. El juez justificó:

«A falta de información, no es comprensible que las cifras en las que se basa esta recomendación solo incluyan a aquellas personas que fueron examinadas según los lineamientos de la OMS para la interpretación de las pruebas de PCR del 20 de enero de 2021. No hay información específica sobre qué valor de CT tuvo un resultado de prueba, si una persona examinada sin síntomas fue examinada nuevamente y luego examinada clínicamente».

Según la propia OMS, las pruebas de PCR no dirían «nada sobre la enfermedad o infección de una persona».

El juez va aún más lejos y señala que los tres criterios para un «caso corona confirmado» establecidos por el ministro de Salud Rudolf Anschober el 23 de diciembre también son inadecuados. Ninguno de estos tres criterios cumpliría los requisitos de la OMS para el término «enfermo / infectado».

Además, el juez también señala que las pruebas de antígenos «son muy defectuosas si no hay síntomas». El tribunal también determinó, con referencia a la Ley de médicos, que sólo un médico tiene derecho a determinar si una persona está enferma o sana

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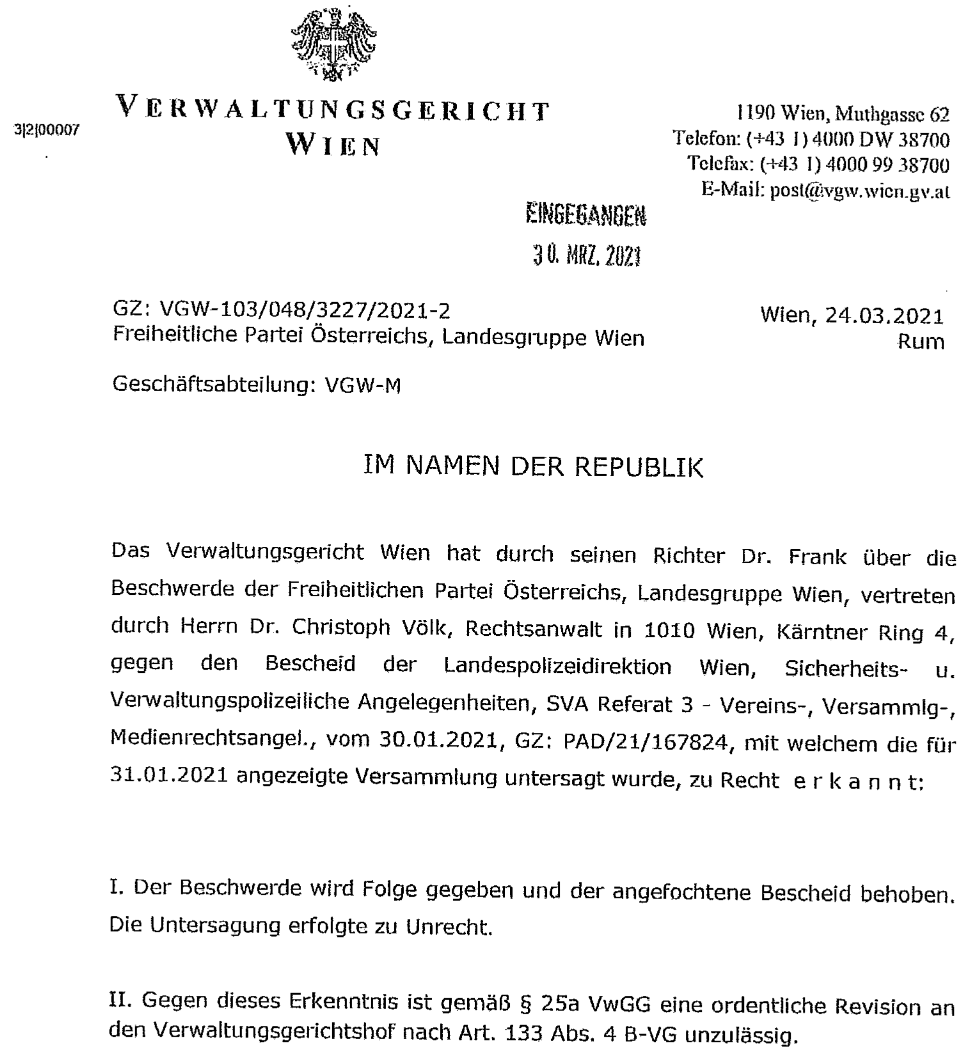

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VERWALTUNGSGERICHT
WIEN

1190 Wien, Muthgasse 62
Telefon: (+43 1) 4000 DW 38700
Telefax: (+43 1) 4000 99 38700
E-Mail: post@vgw.wien.gv.at

EINGEGANGEN
30. MRZ. 2021

GZ: VGW-103/048/3227/2021-2
Freiheitliche Partei Österreichs, Landesgruppe Wien

Wien, 24.03.2021
Rum

Geschäftsabteilung: VGW-M

IM NAMEN DER REPUBLIK

Das Verwaltungsgericht Wien hat durch seinen Richter Dr. Frank über die Beschwerde der Freiheitlichen Partei Österreichs, Landesgruppe Wien, vertreten durch Herrn Dr. Christoph Völk, Rechtsanwalt in 1010 Wien, Kärntner Ring 4, gegen den Bescheid der Landespolizeidirektion Wien, Sicherheits- u. Verwaltungspolizeiliche Angelegenheiten, SVA Referat 3 - Vereins-, Versammlg-, Medienrechtsangel., vom 30.01.2021, GZ: PAD/21/167824, mit welchem die für 31.01.2021 angezeigte Versammlung untersagt wurde, zu Recht erkannt:

I. Der Beschwerde wird Folge gegeben und der angefochtene Bescheid behoben. Die Untersagung erfolgte zu Unrecht.

II. Gegen dieses Erkenntnis ist gemäß § 25a VwGG eine ordentliche Revision an den Verwaltungsgerichtshof nach Art. 133 Abs. 4 B-VG unzulässig.

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DEPARTAMENTO DE
SALUD
GOBIERNO DE PUERTO RICO

GOBIERNO DE PUERTO RICO
DEPARTAMENTO DE SALUD

GUIA PARA EL DIAGNOSTICO DE COVID-19

INTRODUCCION:

El diagnostico de COVID-19, causado por el virus SARS-CoV-2, puede ser retante para los clínicos, por la variedad de síntomas que se han estado presentando y la similitud de estos con otras condiciones respiratorias. Además, el uso de pruebas diagnósticas para identificar al virus SARS-CoV-2 se inserta en otras situaciones de suma importancia como lo es la necesidad de evaluar personas sin síntomas luego de exposición a pacientes confirmados, como también los que no han estado expuestos pero que se les requiere alguna prueba para descartar la posibilidad de que sean portadores asintomáticos de la enfermedad.

Las personas con COVID-19 pueden presentar una gama de síntomas y pueden seguir presentándose otros, a medida que se estudie más la enfermedad. Los mismos pueden ser leves, moderados o severos. Se ha identificado que personas con enfermedad previa del corazón, diabetes o del pulmón, tienen más riesgo de tener síntomas más severos o tener más complicaciones a causa del virus. Los síntomas menos comunes, son; náuseas, vómitos o diarreas.

Los síntomas más comunes de COVID-19, reportados hasta el momento lo son:

- Tos
- Falta de aire
- Fiebre
- Escalofrío
- Dolor muscular
- Dolor de garganta o
- Perdida nueva de o sabor

Síntomas atípicos como manifestaciones cutáneas, hepáticas y síntomas inflamatorios multisistémicos están siendo cada vez más reportados, pero su verdadera incidencia es aún desconocida. También, es importante reconocer la posibilidad de que esta enfermedad se manifieste, de forma inusual, en la población pediátrica.

A continuación, la guía para el diagnóstico de COVID-19, recomendada en consenso por un grupo de reconocidos infectólogos en Puerto Rico, y adoptada por nuestra agencia, para la implantación inmediata. La misma está sujeta a ajustes o cambios, de acuerdo con la evolución de las recomendaciones de las agencias que están manejando esta Pandemia.

A. Cada clínico, ordenará la realización de la prueba que corresponda, de acuerdo con el cernimiento realizado a la paciente:

1. **Pruebas moleculares (PCR):** Este tipo de prueba detecta material del virus (SARS-CoV-2). Es la prueba preferida al momento de evaluar pacientes que se presenten con síntomas sospechosos de COVID-19. Hay varias pruebas disponibles de diferentes compañías, y su sensitividad puede variar. Se estima que esta prueba pueda ser 70% sensitiva y 99% especifica. Por lo que un resultado positivo confirmaría la condición, pero un resultado negativo no descarta el diagnostico. Las pruebas moleculares son las pruebas de elección al momento de evaluar pacientes sintomáticos, pacientes asintomáticos, así como para determinar cuando una persona pueda cesar de mantenerse en aislamiento.
2. **Pruebas de proteínas virales (IFA o antígenos):** Las pruebas de IFA (immunoflourecense assay) son ampliamente usadas para detectar otros virus como HIV e influenza. Su método de implementación puede ser muy variado, pero en el caso de SARS-CoV-2, se usa para detectar proteínas virales por lo que es una prueba de detección directa. Esta prueba se obtiene con un hisopo nasofaríngeo al igual que las pruebas moleculares, pero sus resultados son rápidos. Otra ventaja generalmente es su precio, ya que tienden a ser más accesibles que pruebas moleculares. Su sensitividad y especificidad tienden a ser muy buenas, sobre 90%. Sin embargo, al presente no están disponibles a gran escala y comercialmente.
3. **Pruebas serológicas (IgM, IgG):** Estas pruebas no detectan partículas virales, sino que detectan diferentes respuestas inmunológicas hacia el SARS-CoV-2. Estos anticuerpos se producen en etapas diferentes y siempre hay un desfase entre la enfermedad aguda y la aparición de estos. Se espera que una persona infectada con el virus comience a producir anticuerpos IgM a partir del 5to día. Entre más días pasen, más posibilidad hay de que un paciente infectado produzca una prueba serológica

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positiva. Esto causa una limitación al momento de identificar pacientes agudamente enfermos, síntomas tempranos en la infección, personas asintomáticas, o personas recientemente expuestas a pacientes con COVID-19. Un posible escenario ideal para usar pruebas IgM lo sería en pacientes con síntomas por al menos 5 días o más, en donde no hay disponibilidad cercana para obtener pruebas moleculares. Otro posible escenario para usar pruebas de IgM lo sería en pacientes con síntomas por al menos 5 días o más, altamente sospechosos donde las pruebas moleculares hayan arrojado resultados negativos. De seleccionar la prueba serológica IgM para evaluar un paciente con síntomas y arrojar un resultado positivo, el caso se debe manejar como COVID-19 en todos sus renglones. Esto es independientemente de tener pruebas moleculares (PCR) negativas.

El anticuerpo IgG es un anticuerpo de memoria, ya que tiende a perdurar meses y hasta años. Mayormente se usa para detectar una pasada infección y/o inmunidad. Este anticuerpo tiende a producirse a partir de 2 semanas de una infección, por lo que no se usa para detectar infecciones tempranas/agudas.

En la actualidad no se ha determinado si la presencia de IgG contra SARS-CoV-2 es suficiente para determinar inmunidad para próximas infecciones. Por el momento la detección del anticuerpo IgG podría servir para estimar prevalencia de SARS-CoV-2 en una población.

Las pruebas serológicas tienen la ventaja, al ser pruebas de sangre, de que su resultado no depende de una técnica de colección compleja como los hisopos nasofaríngeos. Pero su mayor desventaja proviene de sus métodos de producción. Hay mucha variedad de pruebas y variedad de detectan áreas de virus distintas, por lo que sus resultados pueden ser inconsistentes. Bajo la orden de emergencia, se permitió la venta de pruebas con poca data dándoles aprobación de FDA. Por tanto, estas pruebas deben ser previamente validadas bajo condiciones de laboratorio que certifiquen la validez de sus resultados.

4. **Otras pruebas en desarrollo (saliva, aliento, etc.):** Aunque surgen muchas noticias de nuevos posibles métodos noveles para diagnosticar SARS-CoV-2, estas pruebas de diagnósticos están en desarrollo y son experimentales. Aun no se conoce cuál será su sensitividad o especificidad comparado con PCR.

Es importante seleccionar la prueba diagnóstica más apropiada para evaluar pacientes con sospechas de SARS-CoV-2. Las pruebas de PCR son las preferidas para la evaluación médica.

Las pruebas serológicas tienen muchas limitaciones para uso cotidiano en pacientes asintomáticos. Por lo tanto, no se recomiendan para uso en CDT, sala de emergencias, evaluación preoperatoria, condición para transferir pacientes entre centros hospitalarios, o como evaluación para empleados de empresas.

Además, tenemos que recalcar que un resultado negativo, de ninguna de las pruebas, descarta que una persona pueda tener el virus SARS-Cov-2. En todos los escenarios se recomienda que las personas continúen las reglas de distanciamiento social y continúen usando el equipo de protección requerido.

B. RESUMEN DE INTERPRETACIÓN DE RESULTADOS DE PRUEBAS PARA EL VIRUS SARS-COV-2 (COVID-19)

PCR	IFA	IgM	IgG	Interpretación
+	-	-	-	Infección temprana (*fase de ventana)
-	+	-	-	Infección temprana (*fase de ventana)
+	+	+	-	Infección temprana con respuesta inmunológica
-	-	+	-	Infección temprana, con posible PCR/IFA falsamente negativo
+	+	+	+	Infección activa prolongada, posiblemente en transición a recuperación
+	+	-	+	Etapa tardía de infección
-	-	-	+	Etapa de recuperación o infección previa

*La fase de ventana se conoce como el periodo que una enfermedad está presente, pero no se ha creado una respuesta de anticuerpos contra la misma. Es un término descriptivo que no altera el diagnostico de una enfermedad, solo utilizado para entender la etapa de la enfermedad

No se recomiendan pruebas serológicas como parte de la evaluación rutinaria en casos sospechosos de SARS-CoV-2 (Covid-19) **. **No se recomienda hacer pruebas serológicas en CDT, sala de emergencias, evaluación preoperatoria, condición para transferir pacientes entre centros hospitalarios, o como evaluación para empleados de empresas

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Guía desarrollada a base del Documento de consenso de la Sociedad de Enfermedades Infecciosas de Puerto Rico. Autores: Dr. Lemuel Martínez, Dr. Humberto Guiot, Dra. Marielys Otero, Dra. Sanet Torres, Dr. Carlos Guzmán, Dra. Glenda González y Dr. Jorge Santana.

Aprobado por:

Dr. Lorenzo González Feliciano MD, MBA, DHA
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Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China

Shiyi Cao[1,11], Yong Gan[1,11], Chao Wang[1,11], Max Bachmann[2], Shanbo Wei[3], Jie Gong[4], Yuchai Huang[1], Tiantian Wang[1], Liqing Li[5], Kai Lu[6], Heng Jiang[7,8], Yanhong Gong[1], Hongbin Xu[1], Xin Shen[1], Qingfeng Tian[9], Chuanzhu Lv[10]✉, Fujian Song[2]✉, Xiaoxv Yin[1]✉ & Zuxun Lu[1]✉

Stringent COVID-19 control measures were imposed in Wuhan between January 23 and April 8, 2020. Estimates of the prevalence of infection following the release of restrictions could inform post-lockdown pandemic management. Here, we describe a city-wide SARS-CoV-2 nucleic acid screening programme between May 14 and June 1, 2020 in Wuhan. All city residents aged six years or older were eligible and 9,899,828 (92.9%) participated. No new symptomatic cases and 300 asymptomatic cases (detection rate 0.303/10,000, 95% CI 0.270–0.339/10,000) were identified. There were no positive tests amongst 1,174 close contacts of asymptomatic cases. 107 of 34,424 previously recovered COVID-19 patients tested positive again (re-positive rate 0.31%, 95% CI 0.423–0.574%). The prevalence of SARS-CoV-2 infection in Wuhan was therefore very low five to eight weeks after the end of lockdown.

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[1] Department of Social Medicine and Health Management, School of Public Health, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei, China. [2] Norwich Medical School, Faculty of Medicine and Health Science, University of East Anglia, Norwich, UK. [3] Wuhan Municipal Health Commission, Wuhan, Hubei, China. [4] Wuhan Centre for Clinical Laboratory, Wuhan, Hubei, China. [5] Department of Management Science and Engineering, School of Economics and Management, Jiangxi Science and Technology Normal University, Nanchang, Jiangxi, China. [6] Tongji Hospital, Huazhong University of Science and Technology, Wuhan, Hubei, China. [7] Centre for Alcohol Policy Research, School of Psychology and Public Health, La Trobe University, Melbourne, VIC, Australia. [8] Melbourne School of Population and Global Health, University of Melbourne, Melbourne, VIC, Australia. [9] School of Public Health, Zhengzhou University, Zhengzhou, Henan, China. [10] Department of Emergency, Hainan Clinical Research Centre for Acute and Critical Diseases, The Second Affiliated Hospital of Hainan Medical University, Haikou, Hainan, China. [11] These authors contributed equally: Shiyi Cao, Yong Gan, Chao Wang. ✉email: lyuchuanzhu@hainmc.edu.cn; Fujian.song@uea.ac.uk; yxx@hust.edu.cn; zuxunlu@yahoo.com

The Coronavirus Disease 2019 (COVID-19) was first reported in December 2019, and was classified as a pandemic by the World Health Organization on March 11, 2020[1]. Following strict lockdown measures, the COVID-19 epidemic was generally under control in China, and the whole country has progressed into a post-lockdown phase. In this phase, countries face new problems and challenges, including how to accurately assess the post-lockdown risk of the COVID-19 epidemic, how to avoid new waves of COVID-19 outbreaks, and how to facilitate the resumption of economy and normal social life. As the city most severely affected by COVID-19 in China, Wuhan had been under lockdown measures from January 23 until April 8, 2020. During the first 2 months after city's reopening, there were only a few sporadic COVID-19 cases in Wuhan (six newly confirmed cases from April 8 to May 10, 2020[2]). However, there was still concern about the risk of COVID-19 in Wuhan, which seriously affected the resumption of industrial production and social services, and hampered the normal lives of residents. In order to ascertain the current status of the COVID-19 epidemic, the city government of Wuhan carried out a comprehensive citywide nucleic acid screening of SARS-CoV-2 infection from May 14, 2020 to June 1, 2020.

The citywide screening of SARS-CoV-2 infection in Wuhan is a mass screening programme in post-lockdown settings, and provided invaluable experiences or lessons with international relevance as more countries and cities around the world entering the post-lockdown phase. In this study, we report the organisation process, detailed technical methods used, and results of this citywide nucleic acid screening.

Results

There were 10,652,513 eligible people aged ≥ 6 years in Wuhan (94.1% of the total population). The nucleic acid screening was completed in 19 days (from May 14, 2020 to Jun 1, 2020), and tested a total of 9,899,828 persons from the 10,652,513 eligible people (participation rate, 92.9%). Of the 9899,828 participants, 9,865,404 had no previous diagnosis of COVID-19, and 34,424 were recovered COVID-19 patients.

The screening of the 9,865,404 participants without a history of COVID-19 found no newly confirmed COVID-19 cases, and identified 300 asymptomatic positive cases with a detection rate of 0.303 (95% CI 0.270–0.339)/10,000. The median age-stratified Ct-values of the asymptomatic cases were shown in Supplementary Table 1. Of the 300 asymptomatic positive cases, two cases came from one family and another two were from another family. There were no previously confirmed COVID-19 patients in these two families. A total of 1174 close contacts of the asymptomatic positive cases were traced, and they all tested negative for the COVID-19. There were 34,424 previously recovered COVID-19 cases who participated in the screening. Of the 34,424 participants with a history of COVID-19, 107 tested positive again, giving a repositive rate of 0.310% (95% CI 0.423–0.574%).

Virus cultures were negative for all asymptomatic positive and repositive cases, indicating no "viable virus" in positive cases detected in this study.

All asymptomatic positive cases, repositive cases and their close contacts were isolated for at least 2 weeks until the results of nucleic acid testing were negative. None of detected positive cases or their close contacts became symptomatic or newly confirmed with COVID-19 during the isolation period. In this screening programme, single and mixed testing was performed, respectively, for 76.7% and 23.3% of the collected samples. The asymptomatic positive rates were 0.321 (95% CI 0.282–0.364)/10,000 and 0.243 (95% CI 0.183–0.315)/10,000, respectively.

The 300 asymptomatic positive persons aged from 10 to 89 years, included 132 males (0.256/10,000) and 168 females (0.355/10,000). The asymptomatic positive rate was the lowest in children or adolescents aged 17 and below (0.124/10,000), and the highest among the elderly aged 60 years and above (0.442/10,000) (Table 1). The asymptomatic positive rate in females (0.355/10,000) was higher than that in males (0.256/10,000).

The asymptomatic positive cases were mainly domestic and unemployed residents (24.3%), retired older adults (21.3%), and public service workers (11.7%) (Fig. 1).

The asymptomatic positive rate in urban districts was on average 0.456/10,000, ranging from 0.317/10,000 in Hongshan to 0.807/10,000 in Wuchang district. A lower rate of asymptomatic positive cases was found in suburban districts (0.132/10,000), ranging from 0.047/10,000 in Xinzhou to 0.237/10,000 in Jiangan district (Fig. 2).

Among the 7280 residential communities in Wuhan, asymptomatic positive cases were identified in 265 (3.6%) communities (only one case detected in 246 communities), while no asymptomatic positive cases were found in other 96.4% communities.

Testing of antibody against SARS-CoV-2 virus was positive IgG (+) in 190 of the 300 asymptomatic cases, indicating that 63.3% (95% CI 57.6–68.8%) of asymptomatic positive cases were actually infected. The proportion of asymptomatic positive cases with both IgM (−) and IgG (−) was 36.7% (95% CI: 31.2–42.4%; $n = 110$), indicating the possibility of infection window or false positive results of the nucleic acid testing (Table 2).

Higher detection rates of asymptomatic infected persons were in Wuchang, Qingshan and Qiaokou districts, and the prevalence of previously confirmed COVID-19 cases were 68.243/10,000, 53.767/10,000, and 100.047/10,000, respectively, in the three districts. Figure 3 shows that districts with a high detection rate of asymptomatic positive persons generally had a high prevalence of confirmed COVID-19 cases ($r_s = 0.729$, $P = 0.002$).

Discussion

The citywide nucleic acid screening of SARS-CoV-2 infection in Wuhan recruited nearly 10 million people, and found no newly confirmed cases with COVID-19. The detection rate of asymptomatic positive cases was very low, and there was no evidence of transmission from asymptomatic positive persons to traced close contacts. There were no asymptomatic positive cases in 96.4% of the residential communities.

Previous studies have shown that asymptomatic individuals infected with SARS-CoV-2 virus were infectious[3], and might subsequently become symptomatic[4]. Compared with symptomatic patients, asymptomatic infected persons generally have low quantity of viral loads and a short duration of viral shedding, which decrease the transmission risk of SARS-CoV-2[5]. In the present study, virus culture was carried out on samples from asymptomatic positive cases, and found no viable SARS-CoV-2 virus. All close contacts of the asymptomatic positive cases tested negative, indicating that the asymptomatic positive cases detected in this study were unlikely to be infectious.

There was a low repositive rate in recovered COVID-19 patients in Wuhan. Results of virus culturing and contract tracing found no evidence that repositive cases in recovered COVID-19 patients were infectious, which is consistent with evidence from other sources. A study in Korea found no confirmed COVID-19 cases by monitoring 790 contacts of 285 repositive cases[6]. The official surveillance of recovered COVID-19 patients in China also revealed no evidence on the infectiousness of repositive cases[7]. Considering the strong force of infection of COVID-19[8–10], it is expected that the number of confirmed cases is associated with the risk of being infected in communities. We

Table 1 Characteristics of asymptomatic positive individuals.

	Total (%)	Asymptomatic positive persons (%)	Detection rate per 10,000 (95% CI)	P value
Total	9,899,828 (100.0)	300 (100.0)	0.303 (0.270-0.339)	
Sex				
Male	5,162,960 (52.2)	132 (44.0)	0.256 (0.214-0.303)	0.005
Female	4,736,868 (47.8)	168 (56.0)	0.355 (0.303-0.413	
Age (years old)				
≤17	969,014 (9.8)	12 (4.0)	0.124 (0.064-0.216)	<0.001
18-44	4,448,230 (44.9)	104 (34.7)	0.234 (0.191-0.283)	
45-59	2,492,943 (25.2)	96 (32.0)	0.385 (0.312-0.470)	
≥60	1,989,641 (20.1)	88 (29.3)	0.442 (0.355-0.545)	
Administrative Districts in Wuhan				
Wuchang	904,636 (9.1)	73 (24.3)	0.807 (0.633-1.015)	<0.001
Qingshan	414,312 (4.2)	23 (7.7)	0.555 (0.352-0.833)	
Qiaokou	583,440 (5.9)	32 (10.7)	0.548 (0.375-0.774)	
Hanyang	717,429 (7.2)	29 (9.7)	0.404 (0.271-0.581)	
Jianghan	524,224 (5.3)	19 (6.3)	0.362 (0.218-0.566)	
Hongshan	1,103,079 (11.1)	35 (11.7)	0.317 (0.221-0.441)	
East Lake High-tech Development Area	782,987 (7.9)	19 (6.3)	0.243 (0.146-0.379)	
Jiangan	800,440 (8.1)	19 (6.3)	0.237 (0.143-0.371)	
Caidian	503,595 (5.1)	11 (3.7)	0.218 (0.109-0.391)	
Jiangxia	671,248 (6.8)	14 (4.7)	0.209 (0.114-0.350)	
Huangpi	979,920 (9.9)	14 (4.7)	0.143 (0.078-0.240)	
Hannan	417,022 (4.2)	4 (1.3)	0.096 (0.026-0.246)	
Dongxihu	777,204 (7.9)	5 (1.7)	0.064 (0.021-0.150)	
Xinzhou	634,408 (6.4)	3 (1.0)	0.047 (0.010-0.138)	
East Lake Scenic Area of Wuhan	85,884 (0.9)	0 (0.0)	0.000 (0.000-0.430)	

χ^2 test was used to assess the association between the detection rate of asymptomatic cases increased and sex and age. Urban districts of Wuhan includes Wuchang, Qingshan, Qiaokou, Hanyang, Jiangan, Jianghan, and Hongshan; Suburban districts of Wuhan includes Hannan, Caidian, Dongxihu, Xinzhou, Jiangxia, Huangpi, East Lake High-tech Development Area, and East Lake Scenic Area of Wuhan.

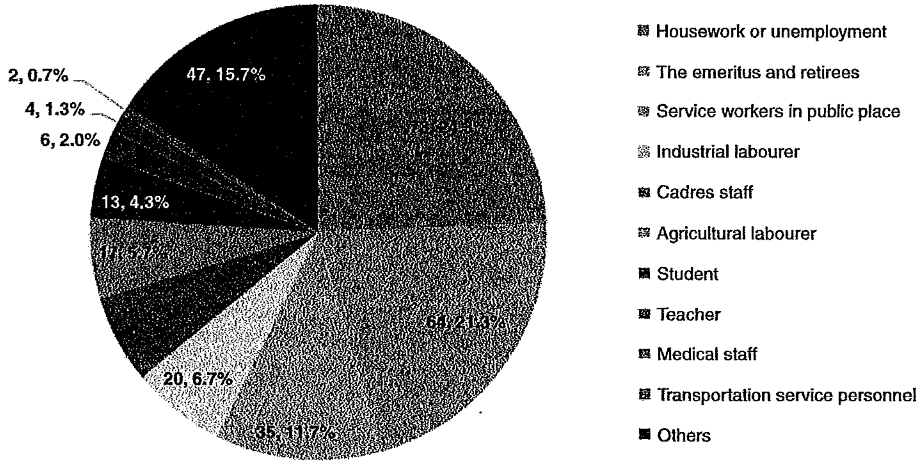

Fig. 1 The occupation distribution of asymptomatic positive cases (%). Note: Others included the self-employed, military personnel, and so on. (Source data are provided as s Source Data file.).

found that asymptomatic positive rates in different districts of Wuhan were correlated with the prevalence of previously confirmed cases. This is in line with the temporal and spatial evolution (especially the long-tailed characteristic) of infectious diseases[11].

Existing laboratory virus culture and genetic studies[9,10] showed that the virulence of SARS-CoV-2 virus may be weakening over time, and the newly infected persons were more likely to be asymptomatic and with a lower viral load than earlier infected cases. With the centralized isolation and treatment of all COVID-19 cases during the lockdown period in Wuhan, the risk of residents being infected in the community has been greatly reduced. When susceptible residents are exposed to a low dose of virus, they may tend to be asymptomatic as a result of their own immunity. Serological antibody testing in the current study found that at least 63% of asymptomatic positive cases were actually infected with SARS-CoV-2 virus. Nonetheless, it is too early to be complacent, because of the existence of asymptomatic positive cases and high level of susceptibility in residents in Wuhan. Public health measures for the prevention and control of COVID-19 epidemic, including wearing masks, keeping safe social distancing in Wuhan should be sustained. Especially, vulnerable populations with weakened immunity or co-morbidities, or both, should continue to be appropriately shielded.

Findings from this study show that COVID-19 was well controlled in Wuhan at the time of the screening programme. After two months since the screening programme (by August 9, 2020), there were no newly confirmed COVID-19 cases in Wuhan.

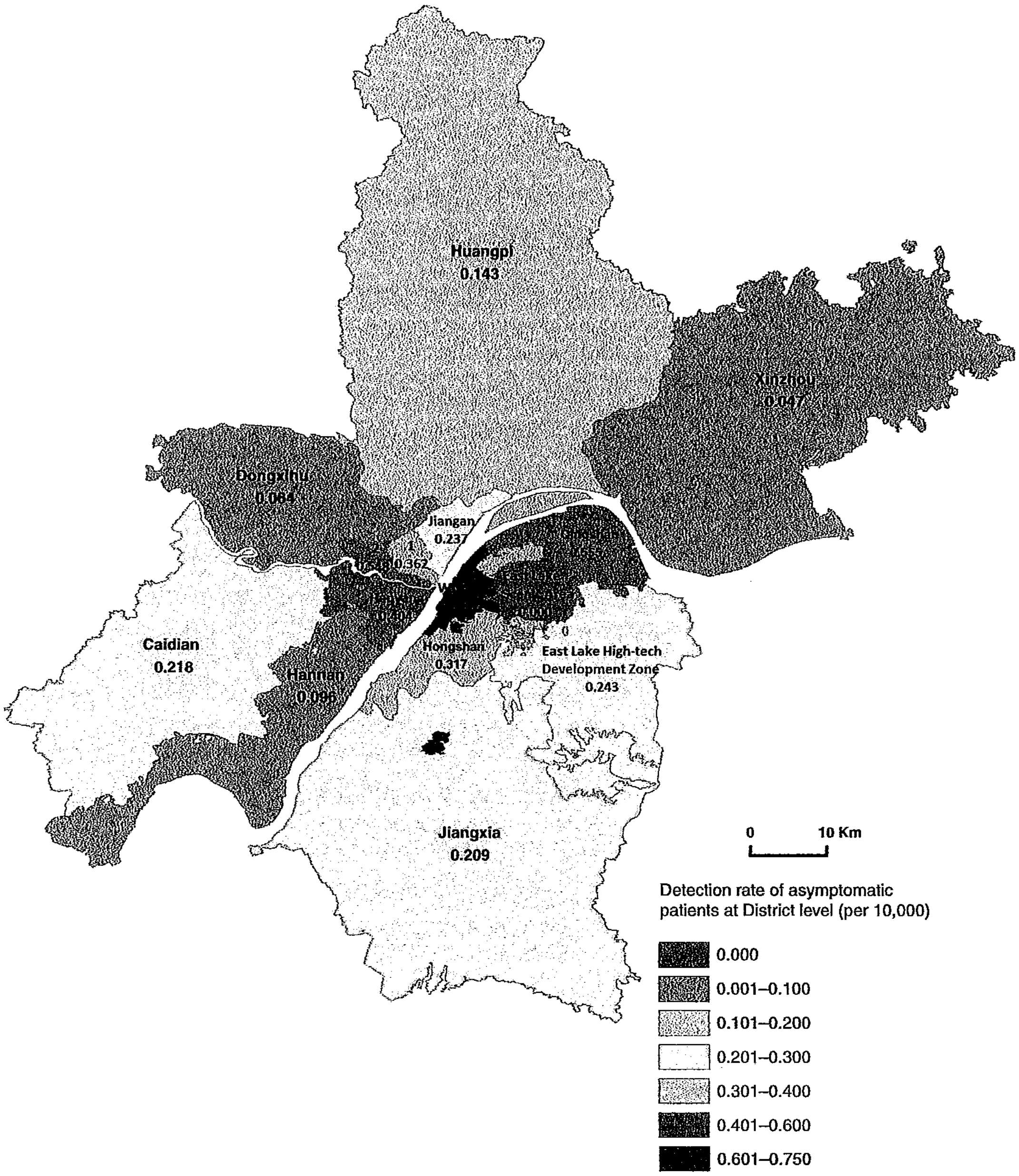
Huangpi
0.143
Xinzhou
0.047
Dongxihu
0.064
Jiangan
0.237
1
0.362
Caidian
0.218
Hannan
0.096
Hongshan
0.317
0
East Lake High-tech
Development Zone
0.243
Jiangxia
0.209
0
10 Km
Detection rate of asymptomatic patients at District level (per 10,000)
0.000
0.001–0.100
0.101–0.200
0.201–0.300
0.301–0.400
0.401–0.600
0.601–0.750

Fig. 2 The geographic distribution of the detection rate of asymptomatic positive cases. Note: 1 represents Jianghan district; 2 represents Qiaokou district. (Source data are provided as s Source Data file.).

Table 2 Results of the detection of antibody in 300 asymptomatic positive persons.

IgM Results	IgG	Asymptomatic positive persons	% (95% CI)
–	+	161	53.7 (47.8–59.4)
–	–	110	36.7 (31.2–42.4)
+	+	29	9.7 (6.6–13.6)
+	–	0	0.0 (0.0–1.2)

"–" indicates negative; "+" indicates positive.

Further testing of SARS-CoV-2 in samples collected from market environment settings in Wuhan were conducted, and found no positive results after checking a total of 52,312 samples from 1795 market setting during June 13 to July 2, 2020[12].

This study has several limitations that need to be discussed. First, this was a cross-sectional screening programme, and we are unable to assess the changes over time in asymptomatic positive and reoperative results. Second, although a positive result of nucleic acid testing reveals the existence of the viral RNAs, some false negative results were likely to have occurred, in particular due to the relatively low level of virus loads in asymptomatic infected individuals, inadequate collection of samples, and limited accuracy of the testing technology[13]. Although the screening programme provided no direct evidence on the sensitivity and specificity of the testing method used, a meta-analysis reported a

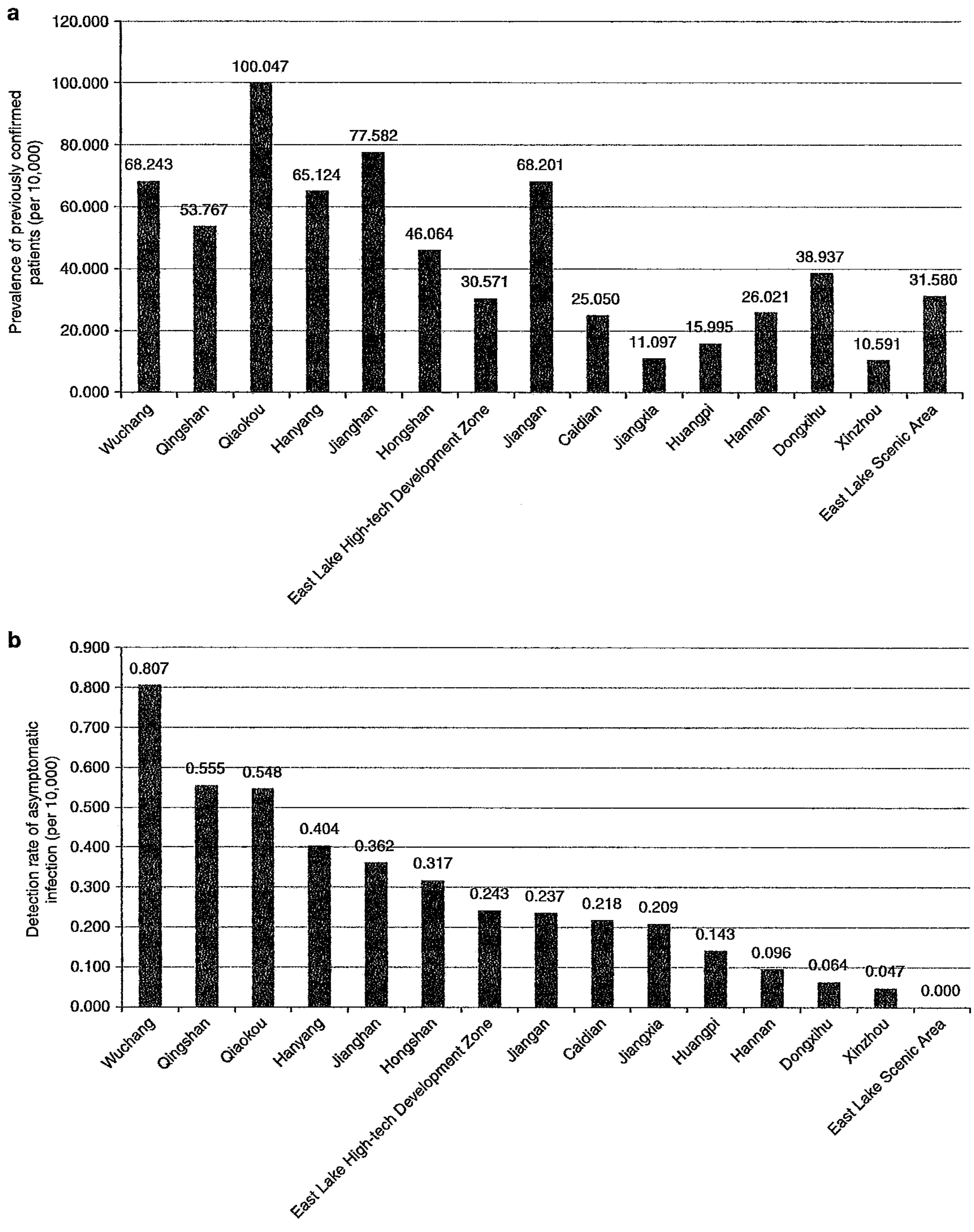

Fig. 3 The prevalence of previously confirmed patients and the detection rate of asymptomatic positive cases of COVID-19 in each district in Wuhan. **a** The prevalence of previously confirmed patients of COVID-19 in each district in Wuhan. **b** The detection rate of asymptomatic positive cases of COVID-19 in each district in Wuhan. (Source data are provided as s Source Data file.).

pooled sensitivity of 73% (95% CI 68–78%) for nasopharayngeal and throat swab testing of COVID-19[14]. Testing kits used in the screening programme were publicly purchased by the government and these kits have been widely used in China and other countries. Multiple measures were taken to possibly minimise false negative results in the screening programme. For example, standard training was provided to health works for sample collection to ensure the sample quality. The experiment procedures, including specimen collection, extraction, PCR, were according to official guidelines (Supplementary Note 1). For the real-time RT-PCR assay, two target genes were simultaneously tested. Even so, false negative results remained possible, particularly in any mass screening programmes. However, even if test sensitivity was as low as 50%, then the actual prevalence would be twice as high as reported in this study, but would still be very low. Around 7.1% of eligible residents did not participate in the citywide nucleic acid screening and the screening programme did not collect detailed data on reasons for nonparticipation, which is a limitation of this study. Although there were no official statistics, a large number of migrant workers and university students left Wuhan before the lockdown, joining their families in other cities or provinces for traditional Chinese New Year. Therefore, it is likely that most nonparticipants were not in Wuhan at the time of the screening. The main objective of the screening programme was to assess the risk of COVID-19 epidemic in residents who were actually living in the post-lockdown Wuhan. Therefore, the estimated positive rates are unlikely to be materially influenced by nonparticipation of residents who were not in Wuhan or some residents who did not participate in the screening for other reasons. Moreover, people who left Wuhan were the target population for monitoring in other provinces and cities and were required to take nucleic acid testing. Although there was no official statistics showing the positive rate of nucleic acid testing in this population, there was no report that shown a higher positive rate of nucleic acid testing than our findings.

In summary, the detection rate of asymptomatic positive cases in the post-lockdown Wuhan was very low (0.303/10,000), and there was no evidence that the identified asymptomatic positive cases were infectious. These findings enabled decision makers to adjust prevention and control strategies in the post-lockdown period. Further studies are required to fully evaluate the impacts and cost-effectiveness of the citywide screening of SARS-CoV-2 infections on population's health, health behaviours, economy, and society.

Methods

Study population and ethical approvals. Wuhan has about 11 million residents in total, with seven urban and eight suburban districts. Residents are living in 7280 residential communities (or residential enclosures, "xiao-qu" in Chinese), and each residential community could be physically isolated from other communities for preventing transmission of COVID-19.

The screening programme recruited residents (including recovered COVID-19 patients) currently living in Wuhan who were aged ≥6 years (5,162,960 males, 52.2%). All participants provided written or verbal informed consent after reading a statement that explained the purpose of the testing. For participants who aged 6–17 years old, consent was obtained from their parents or guardians. The study protocol for an evaluation of the programme based on anonymized screening data was approved by the Ethics Committee of the Tongji Medical College Institutional Review Board, Huazhong University of Science and Technology, Wuhan, China (No. IROG0003571).

Organizational guarantee and community mobilization. A citywide nucleic acid screening group was formed, with specialized task teams contributing to comprehensive coordination, technical guidance, quality control, participation invitation, information management, communication, and supervision of the screening. The city government invested 900 million yuan (RMB) in the testing programme. From 14 May to 1 June 2020, in the peak time, up to 2907 sample collection sites were functioning at the same time in Wuhan. Each sample collection site had an assigned sample collection group, including several health professionals (staffed according to the number of communities' residents), 2–4 community managers, 1–2 police officers, and 1–2 inspectors. The sampling sites were set up based on the number and accessibility of local residents. Local community workers were responsible for a safe and orderly sampling process to minimise the waiting time. In addition, mobile sampling teams were formed by primary health care professionals and volunteers to conduct door-to-door sampling for residents who had physical difficulties or were unable to walk.

About 50,000 health professionals (mainly doctors and nurses from community health centers) and more than 280,000 person-times of community workers and volunteers contributed to sample collection, transport of equipment and samples collected, arrangement of participation process, and maintaining order of sampling sites. Public information communication and participant invitation were implemented through mass media, mobile messages, WeChat groups, and residential community broadcasts, so as to increase residents' awareness and the participation.

Acquisition, preservation, and transport of samples. All sampling personnel received standard training for the collection of oropharyngeal swab samples. To minimise the risk of cross-infection, the sampling process strictly followed a disinfection process and environmental ventilation were ensured. The collected samples were stored in a virus preservation solution or immersed in isotonic saline, tissue culture solution, or phosphate buffer (Supplementary note 1). Then, all samples were sent to testing institutions within 4 h using delivery boxes for biological samples refrigerated with dry ice to guarantee the stability of nucleic acid samples.

Technical methods for laboratory testing of collected samples. A total of 63 nucleic acid testing laboratories, 1451 laboratory workers and 701 testing equipment were involved in the nucleic acid testing. Received samples were stored at 4 °C and tested within 24 h of collection. Any samples that could not be tested within 24 h were stored at −70 °C or below (Supplementary note 1). In addition to "single testing" (i.e., separate testing of a single sample), "mixed testing" was also performed for 23% of the collected samples to increase efficiency, in which five samples were mixed in equal amounts, and tested in the same test tube. If a mixed testing was positive for COVID-19, all individual samples were separately retested within 24 h[15].

Details regarding technical methods for sequencing and virus culture were provided in Supplementary note 1. Real-time reverse transcriptase-polymerase chain reaction (RT-PCR) assay method was used for the nucleic acid testing. We simultaneously amplified and tested the two target genes: open reading frame 1ab (ORF1ab) and nucleocapsid protein (N) (Supplementary Note 1). A cycle threshold value (Ct-value) less than 37 was defined as a positive result, and no Ct-value or a Ct-value of 40 or more was defined as a negative result. For Ct-values ranging from 37 to 40, the sample was retested. If the retest result remained less than 40 and the amplification curve had obvious peak, the sample was classified as positive; otherwise, it was reported as being negative. These diagnostic criteria were based on China's official recommendations[16].

For asymptomatic positive cases, virus culture was carried out in biosafety level-3 laboratories. The colloidal gold antibody test was also performed for asymptomatic positive cases (Supplementary note 1). All testing results were double entered into a specifically designed database, and managed by the Big Data and Investigation Group of the COVID-19 Prevention and Control Centre in Wuhan, which was established to collect and manage data relevant to the COVID-19 epidemic.

Participant data collection and management. Before sample collection, residents electronically (using a specifically designed smartphone application) self-uploaded their personal information, including ID number, name, sex, age, and place of residence. Then, the electronic machine system generated a unique personal barcode and stuck it on the sample tube to ensure the match between the sample and the participant. Then trained staff interviewed each individual regarding the history of COVID-19 and previous nucleic acid testing. There was a database of confirmed COVID-19 cases in Wuhan, which can be used to validate the self-reported previous COVID-19 infection. All information was entered into a central database. The testing results were continually uploaded to the central database by testing institutions. Contact tracing investigations were conducted on participants who tested positive for SARS-CoV-2, to track and manage their close contacts. The pre-existing unique identification code for each resident was used as the programme's identification number, to ensure information accuracy during the whole process of screening, from sampling, nucleic acid testing, result reporting, the isolation of detected positive cases, and tracing of close contacts of positive cases. All screening information was kept strictly confidential and was not allowed to be disclosed or used for other purposes other than clinical and public health management. Personal information of asymptomatic positive cases was only disclosed to designated medical institutions and community health centres for the purpose of medical isolation and identification of close contacts. Researcher was blind to the study hypothesis during data collection.

Biological security guarantee. Nucleic acid testing was performed in biosafety level-2 (BSL-2) laboratories, and virus culture was conducted in biosafety level-3 laboratories. Sampling and testing personnel adopted the personal protective measures according to the standard of biosafety level-3 laboratories. Participating laboratories implemented control measures to guarantee biological safety in accordance with relevant regulations[17].

Result query and feedback. Two to three days after sample collection, participants could inquire about their test results using WeChat or Alipay application by their unique ID numbers. The results included text descriptions of nucleic acid testing and coloured health codes. A green coloured health code refers to a negative result, and a red coloured health code indicates a positive result.

Definition and management of identified confirmed cases and close contacts. In this study, all confirmed COVID-19 cases were diagnosed by designated medical institutions according to National Guidelines for the Prevention and Control of COVID-19 (Supplementary Note 2). Asymptomatic positive cases referred to individuals who had a positive result during screening, and they had neither a history of COVID-19 diagnosis, nor any clinical symptoms at the time of the nucleic acid testing. Close contacts were individuals who closely contacted with an asymptomatic positive person since 2 days before the nucleic acid sampling[16]. Repositive cases refer to individuals who recovered from previously confirmed COVID-19 disease and had a positive testing again in the screening programme. All repositive cases, asymptomatic positive persons, and their close contacts were isolated for at least 2 weeks in designated hotels managed by primary health care professionals, and they were released from isolation only if two consecutive nucleic acid tests were negative.

Statistical analysis. Detection rate of asymptomatic positive or repositive cases was calculated by dividing the number of individuals with a positive result of nucleic acid testing by the number of participants tested. Because of extremely low detection rates, we calculated 95% confidence intervals of estimated proportions using Pearson–Klopper exact method, implemented through R package "binom" version 1.1-1[18]. SPSS version 22.0 was used for other statistical analyses. We analyzed the distribution of asymptomatic positive cases and assessed the Spearman correlation between the asymptomatic positive rate and the prevalence of previously confirmed COVID-19 cases in different districts of Wuhan. Differences in asymptomatic positive rates by sex and age groups were assessed using the χ^2 test. ArcGIS 10.0 was used to draw a geographic distribution map of asymptomatic positive cases. A value of $P < 0.05$ (two-tailed) was considered statistically significant.

Reporting summary. Further information on research design is available in the Nature Research Reporting Summary linked to this article.

Data availability

Detailed data directly used to generate each figure or table of this study are available within the article, Supplementary Information and source data are provided with this paper.

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Author contributions

S.Y.C., C.W., X.X.Y., and Z.X.L. conceived the study. C.W., Y.C.H., T.T.W., K.L., H.B.X., and X.S. participated in the acquisition of data. S.B.W. and J.G. were responsible for the on-site specimen collection, laboratory testing quality evaluation, and control. Y.C.H., T.T.W., and L.Q.L. analyzed the data. H.J., Y.H.G., and F.J.S. gave advice on methodology. Q.F.T. and C.Z.L. investigated the responses to the citywide nucleic acid testing among residents lived in outside of Wuhan city. S.Y.C., Y.G., C.W., and X.X.Y. drafted the manuscript, Y.G., M.B., and F.J.S. revised the manuscript, and M.B., C.Z.L., and F.J.S. critically commented and edited the manuscript. All authors read and approved the final manuscript. Z.X.L. is the guarantor of this study.

Competing interests

The authors declare no competing interests.

Additional information

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Correspondence and requests for materials should be addressed to C.L., F.S., X.Y. or Z.L.

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Dr. Harvey Risch is Professor of Epidemiology in the Department of Epidemiology and Public Health at the Yale School of Public Health and Yale School of Medicine. Dr. Risch received his MD degree from the University of California San Diego and PhD from the University of Chicago. After serving as a postdoctoral fellow in epidemiology at the University of Washington, Dr. Risch was a faculty member in epidemiology and biostatistics at the University of Toronto before coming to Yale.

- **Postdoctoral Fellow**
  School of Public Health and Community Medicine, University of Washington (1983)
- **PhD**
  University of Chicago (1980)
- **MD**
  University of California, San Diego (1976)
- **BS**
  California Institute of Technology (1972)

Statement of Harvey A. Risch, MD, PhD
Professor of Epidemiology, Yale School of Public Health

Senators and colleagues: thank you for convening this hearing. We all understand the endemic disease that we are facing, that we have to face it head-on and not hide from it hoping that it will go away. I want to give you my perspective.

In May of this year I observed that results of studies of a drug suggested to treat Covid, hydroxychloroquine, were being misrepresented by what I thought at the time was sloppy reporting. We have heard from Dr. McCullough how Covid disease progresses in phases, from viral replication, to florid pneumonia to multi-organ attack. Viral replication is an outpatient condition, but the pneumonia that fills the lungs with immune-system debris is hospitalizable and potentially life-threatening. We have also heard how each phase, each pathologic aspect of the disease, has to have its own specific treatments that apply to its own biologic mechanisms. Thus, I was frankly astounded that studies of hospital treatments were being represented as applying to outpatients, in violation of what I learned in medical school about how to treat patients.

We are now finally coming to address why over the last six months, our government research institutions have invested billions of dollars in expensive patent medication and vaccine development but almost nothing in early outpatient treatment, the first line of response to managing the pandemic. It is not that we lacked candidate medications to study, we have had a number of promising agents. But I believe that the early-on conflation of hospital with outpatient disease served to imply that treatment of outpatient disease had been studied and found ineffective. This illogical premise motivated me to look at the evidence for outpatient treatment.

I reiterate: we are considering the evidence for early treatment of high-risk outpatients to prevent hospitalization and mortality. That is it. Treatment starting in the first five days or so after the onset of symptoms. Treatment of older patients or patients with chronic conditions such as diabetes, obesity, heart diseases, lung diseases, kidney diseases, immune-system diseases, survivors of cancer etc. These are the people most likely to die from Covid, and they are the people most needing protection. I have sought to obtain reports of every study of every medication pertaining to early treatment of high-risk outpatients. I monitor the literature daily. And what I have found is actually quite remarkable. What I have observed is that while there have been positive reports about a number of drugs, every study of outpatient use of one drug, hydroxychloroquine, with or without accompanying agents, has shown substantial benefit in reducing risks of hospitalization and mortality.

These studies break down into two major types. The first is double-blinded, randomized controlled trials, and the second is non-randomized but still controlled trials. You have heard from various government and scientific personalities that randomized controlled trials provide the strongest form of evidence. Many of these people have also claimed that randomized trials provide the only trustworthy form of evidence. There is some truth in these assertions, but there is also lots of falsehood. We know for example that the great majority of drugs used to treat heart diseases were established with non-randomized trials. Cholesterol-lowering drugs were in widespread use before randomized trials were ever done. Azithromycin, the most commonly used antibiotic in children, was not established by randomized trials. The idea that only randomized trials provide trustworthy evidence is a simplistic notion that may sound good in theory, but the comparison between randomized and non-randomized trials is something that has actually been extensively studied in the medical literature. I am an epidemiologist because even though I love biological theories, I develop them all the time to study how nature works, but it is from the human empirical data that we learn how indeed nature works.

And we have huge amounts of empirical data to show that randomized trials and their corresponding non-randomized trials give the same answers. Dr. Tom Frieden, previously Director of the CDC, in 2017 wrote an extensive essay in the New England Journal of Medicine showing that non-randomized trials can provide fully compelling evidence, especially when they are done carefully to account for reasons why patients received the drugs, and importantly, when circumstances are such that the cost of waiting for randomized trials involves major sickness and mortality as we have been experiencing this year. But Dr. Frieden's essay, as authoritative as it is, provides only snapshots of the empirical evidence for his observations. The real evidence comes from a meta-analysis of meta-analyses done by the Cochrane Library Consortium, a British international organization formed to organize medical research findings to facilitate evidence-based choices about health interventions. The Cochrane investigators examined what involve tens of thousands of comparisons between randomized trials and their non-randomized counterparts and found that the two types of studies arrived at virtually identical conclusions. This is the real evidence about why good non-randomized trials comprise evidence every bit as important as randomized trials. Large amounts of consistent empirical data are the evidence, not plausible but simplistic assumptions, no matter who says them.

So what did I find about hydroxychloroquine in early use among high-risk outpatients? The first thing is that hydroxychloroquine is exceedingly safe. Common sense tells us this, that a medication safely used for 65 years by hundreds of millions of people in tens of billions of doses worldwide, prescribed without routine screening EKGs, given to adults, children, pregnant women and nursing mothers, must be safe when used in the initial viral-replication phase of an illness that is similar at that point to colds or flu. In fact, a study by researchers at the University of Oxford showed that in 14 large international medical-records databases of older rheumatoid arthritis patients, no significant differences were seen in all-cause mortality for patients who did or did not use hydroxychloroquine. The Oxford investigators also looked at cardiac arrhythmias and found no increase for hydroxychloroquine users. This was in more than 900,000 hydroxychloroquine users. This is examined at length in my paper in the American Journal of Epidemiology in May. Now, the FDA posted a warning on July 1 on its website about hydroxychloroquine used in outpatients, but we can discuss this later; the FDA has had no systematic evidence in outpatients and erroneously extrapolated from hospital inpatients to outpatients, what I said earlier was invalid.

About studies of hydroxychloroquine early use in high-risk outpatients, every one of them, and there are now seven studies, has shown significant benefit: 636 outpatients in São Paulo, Brazil; 199 clinic patients in Marseille, France; 717 patients across a large HMO network in Brazil; 226 nursing-home patients in Marseille; 1,247 outpatients in New Jersey; 100 long-term care institution patients in Andorra (between France and Spain); and 7,892 patients across Saudi Arabia. All these studies pertain to the early treatment of high-risk outpatients—and all showed about 50 percent or greater reductions in hospitalization or death. The Saudi study was a national study and showed 5-fold reduction in mortality for hydroxychloroquine plus zinc vs zinc alone. Not a single fatal cardiac arrhythmia was reported among these thousands of patients attributable to the hydroxychloroquine. These are the non-randomized but controlled trials that have been published.

Now we also know that all of the outpatient randomized controlled trials this year also together show statistically significant benefit. These six studies comprised generally much younger patients, only a fraction of whom were at high risk, so they individually had too few hospitalizations or deaths to be statistically significant. But they all suggested lower risks with hydroxychloroquine use, and when they were analyzed together in meta-analysis as my colleagues and I found, this lower risk was statistically significant across the studies.

We have spent the last six months with formal government policies and warnings against early outpatient treatment, with large government investments in vaccines and expensive new treatments yet to be proven and almost no support of inexpensive but useful medications, and a quarter of a million Americans have died from this mismanaged approach. Even with newly promising vaccines, we have almost no information about how they will perform in older and high-risk patients, in whom respiratory virus vaccines are known to have weak efficacy; it will be a number of months before they become widely available; and we don't know how long vaccine immunity will last, or even if the vaccines will work for the newly increasing mutant strains of the virus. As I have said on many occasions, the evidence for benefit of hydroxychloroquine used early in high-risk outpatients is extremely strong, and the evidence against harm is also equally strong. This body of evidence dramatically outweighs the risk/benefit evidence for remdesivir, monoclonal antibodies or the difficult to use bamlanivimab that the FDA has approved for emergency use authorizations while denying the emergency use authorization for hydroxychloroquine. This egregious double standard for hydroxychloroquine needs to be overturned immediately and its emergency use authorization application approved. This is how we will get on the road to early outpatient treatment and the major curtailment of mortality. Thank you.

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COVID-19 outpatients: early risk-stratified treatment with zinc plus low-dose hydroxychloroquine and azithromycin: a retrospective case series study

Roland Derwand[a,1], Martin Scholz[b,1,*], Vladimir Zelenko[c]

[a] *Alexion Pharma Germany GmbH, 80687, Munich, Germany*
[b] *Heinrich-Heine-University, Düsseldorf, Moorenstr. 5, 40225, Düsseldorf, Germany*
[c] *Medical Group Practice, Monroe, NY, 10950, USA*

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ABSTRACT

The aim of this study was to describe the outcomes of patients with coronavirus disease 2019 (COVID-19) in the outpatient setting after early treatment with zinc, low-dose hydroxychloroquine and azithromycin (triple therapy) dependent on risk stratification. This was a retrospective case series study in the general practice setting. A total of 141 COVID-19 patients with laboratory-confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the year 2020 were included. The main outcome measures were risk-stratified treatment decision and rates of hospitalisation and all-cause death. A median of 4 days [interquartile range (IQR) 3–6 days; available for $n = 66/141$ patients] after the onset of symptoms, 141 patients (median age 58 years, IQR 40–67 years; 73.0% male) received a prescription for triple therapy for 5 days. Independent public reference data from 377 confirmed COVID-19 patients in the same community were used as untreated controls. Of 141 treated patients, 4 (2.8%) were hospitalised, which was significantly fewer ($P < 0.001$) compared with 58 (15.4%) of 377 untreated patients [odds ratio (OR) = 0.16, 95% confidence interval (CI) 0.06–0.5]. One patient (0.7%) in the treatment group died versus 13 patients (3.4%) in the untreated group (OR = 0.2, 95% CI 0.03–1.5; $P = 0.12$). No cardiac side effects were observed. Risk stratification-based treatment of COVID-19 outpatients as early as possible after symptom onset using triple therapy, including the combination of zinc with low-dose hydroxychloroquine, was associated with significantly fewer hospitalisations.

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1. Introduction

In December 2019, the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) started as an outbreak in Wuhan, China. This coronavirus has spread rapidly as a pandemic around the world [1], causing coronavirus disease 19 (COVID-19) pneumonia, acute respiratory distress syndrome (ARDS), cardiac injury, liver and renal injury, thrombosis and death [2].

As of June 2020, the diagnosis and treatment of COVID-19 have been almost exclusively studied from an inpatient perspective, including intensive care with mechanical ventilation. Only one study has described the characteristics and key health outcomes of COVID-19 diagnosed patients in an outpatient setting [3]. This is surprising as primary care physicians often see COVID-19 patients first. Thus, they could play a critical role in early diagnosis, treatment and management of disease progression and virus spread. This assumption is supported by the established principle in medicine that speed of eradication is linked to the outcome of life-threatening infections [4].

The early clinical phase of COVID-19 has not been the focus of much research so far, even though timing of antiviral treatment seems to be critical [5]. The optimal window for therapeutic intervention would seem to be before the infection spreads from the upper to lower respiratory tract and before severe inflammatory reaction ensues [6]. Therefore, diagnosis and treatment of COVID-19 outpatients as early as possible, even based on clinical diagnosis only, may have been an underestimated first step to slow down or even stop the pandemic more effectively. Based on clinical application principles of antiviral therapies, as demonstrated in the case

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* Corresponding author. Tel.: +49 89 1218 9349, +49 179 541 04 77.
E-mail address: scholzmartin19@gmail.com (M. Scholz).

[1] These two authors contributed equally to this article.

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of influenza A [7], antiviral treatments should be used early in the course of infection.

Due to the lack of a vaccine or SARS-CoV-2 specific therapies, the proposed use of repurposed antiviral drugs remains a valid practical consideration [8]. One of the most controversial drugs during the current SARS-CoV-2 pandemic is the well-known oral antimalarial drug hydroxychloroquine (HCQ), routinely used in the treatment of autoimmune diseases such as rheumatoid arthritis and systemic lupus erythematosus (SLE) [9,10]. HCQ is currently listed as an essential medication for SLE by the World Health Organization (WHO) [11]. With more than 5.6 million prescriptions in the USA, HCQ was the 128th most commonly prescribed medication in 2017 [12]. In the meantime, the first observational studies concluding beneficial therapeutic effects of HCQ as monotherapy or in combination with the antibiotic azithromycin were reported just a few weeks after the start of the SARS-CoV-2 outbreak [13]. All studies that used HCQ with rather contradictory results were in hospitalised and often sicker patients [13–16], and one publication was recently withdrawn [17,18]. As of June 2020, no studies of COVID-19 outpatients treated with HCQ at an early stage of the disease have been reported.

The antiviral effects of HCQ are well documented [19]. It is also known that chloroquine, and probably HCQ, have zinc ionophore characteristics, increasing intracellular zinc concentrations [20]. Zinc itself is able to inhibit coronavirus RNA-dependent RNA polymerase (RdRp) activity [21]. It has been hypothesised that zinc may enhance the efficacy of HCQ in treating COVID-19 patients [22]. The first clinical trial results confirming this hypothesis were recently published as a preprint [23]. Nevertheless, many studies with HCQ as monotherapy or in combination with the antibiotic azithromycin have been inconclusive so far [13–16]. In all of these studies, HCQ was used later than 5 days after the onset of symptoms when hospitalised patients most likely had already progressed to stage II or III of the disease [6]. Regardless of the established antiviral effects of zinc and that many COVID-19 patients are prone to zinc deficiency, dependent on co-morbidities and drug treatments [22], none of these studies were designed to include zinc supplementation as combination treatment.

This first retrospective case series study of COVID-19 outpatients was done to show whether (i) a simple-to-perform outpatient risk stratification might allow for a rapid treatment decision shortly after onset of symptoms and (ii) whether the 5-day triple therapy with zinc, low-dose HCQ and azithromycin might result in fewer hospitalisations and fatalities compared with relevant public reference data of untreated patients.

2. Methods

2.1. Setting

This retrospective case series study analysed data from COVID-19 outpatients with confirmed SARS-CoV-2 infection treated in a community in New York State, USA, between 18 March 2020 and 14 May 2020. The outcome of patients treated with a specific triple therapy was compared with public reference data of patients in the same community who were not treated with this therapy.

2.2. Confirmation of COVID-19 diagnosis

The COVID-19 diagnosis was confirmed if patients tested positive for SARS-CoV-2 by PCR of nasal or pharyngeal swab specimens (majority of tests by Roche, Basel, Switzerland; 99.1% sensitivity and 99.7% specificity; other tests used with lower frequency included: DiaSorin: 500 copies/mL; Thermo Fisher: 10 genomic copy equivalents/reaction; Seegene: 1250 copies/mL; Hologic: $TCID_{50}/mL$: 1×10^{-2}) or retrospectively by IgG detection tests [DiaSorin: sensitivity 97.6% ($\geq$15 days after diagnosis), specificity 99.3%; Diazyme: sensitivity 91.2%, specificity 97.3%]. Only patients who had a record of a positive test result were included in the analysis. The PCR assays were authorised by the US Food and Drug Administration (FDA) without clinical sensitivity/specificity data owing to the urgent nature of the pandemic. Only one positive test was necessary for the patient to be included in the retrospective analysis.

2.3. Patients

Sequentially consecutive COVID-19 outpatients aged >18 years at diagnosis were included in the analysis as the treatment group. All patients were White. Patients received a prescription for triple therapy only if they met one of the following risk stratification requirements during a medical office-based or telehealth consultation: Group A, age >60 years, with or without clinical symptoms; Group B, age $\leq$60 years and shortness of breath (SOB); or Group C, age $\leq$60 years, clinically symptomatic and with at least one of the following co-morbidities: hypertension, hyperlipidaemia, diabetes mellitus, obesity [body mass index (BMI) $\geq$ 30 kg/m^2], cardiovascular disease, heart failure, history of stroke, history of deep vein thrombosis or pulmonary embolism, asthma, chronic obstructive pulmonary disease (COPD), other lung disease, kidney disease, liver disease, autoimmune disease or history of cancer. Pregnant women, if any, were also included in this group.

Laboratory-confirmed COVID-19 patients from the same community who were not treated with the described triple therapy and their related outcome data represented the untreated control group, which comprised both low-risk and high-risk patients (public reference data).

2.4. Procedure and treatment

Data for treated patients were collected from electronic health records in the year 2020. Demographics, as reported by the patient, and current medical history of hypertension, hyperlipidaemia, diabetes mellitus, obesity (BMI $\geq$ 30 kg/m^2), cardiovascular disease, heart failure, stroke, asthma, COPD, other lung disease, kidney disease, liver disease, autoimmune disease, history of cancer, thyroid disease psychiatric disorder or pregnancy were collected.

The presence of the following clinical symptoms of treated patients was documented: cough/dry cough; fever; SOB; changes to or no smell or taste; sore throat; headache; runny nose/clear rhinorrhoea; sinus congestion; diarrhoea/vomiting; cold symptoms; feeling sick; weakness; and low back pain. If reported, the number of days since onset of symptoms was documented.

The following vital signs, if available, were collected and documented: heart rate (beats/min), respiratory rate (breaths/min), systolic and diastolic blood pressure (mmHg), body temperature (°C), oxygen saturation measured by pulse oximetry (O_2 %), body weight (kg) and/or BMI.

The main co-medications were characterised based on primary care prescriptions active at the time of diagnosis, documented as categorical variables, included beta-blockers, angiotensin-converting enzyme inhibitors, angiotensin 2 antagonists, calcium channel blockers, hydrochlorothiazide, statins, bronchodilators, antidiabetics and insulin.

Only diagnosed COVID-19 patients who met the defined risk stratification requirements of group A, B or C received a prescription for the following triple therapy for 5 consecutive days in addition to standard supportive care: zinc sulfate (220 mg capsule once daily, containing 50 mg elemental zinc); HCQ (200 mg twice daily); and azithromycin (500 mg once daily). No loading dose was used. Patients who did not meet the risk stratification requirements received standard of care to treat common upper respiratory

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tract infections. Patients were not treated with HCQ if they had known contraindications, including QT prolongation, retinopathy or glucose-6-phosphate dehydrogenase deficiency. As usual and following best practice, patients were informed about possible drug-related side effects. Reported events, if any, were documented as required.

Selection of the used zinc supplement and of drugs, dosages and the combination thereof were based on treatment guidelines, positive reports from other countries such as South Korea, emerging first clinical evidence, and based on the discretion of the treating physicians.

2.5. Outcomes

Two outcomes were studied: COVID-19 related hospital admission and all-cause death during time of follow-up of ≥28 days in the treatment group and in the untreated control group (public reference). The outcome of COVID-19 patients in the untreated control group was reported by the responsible health department.

2.6. Statistical analyses

Only patients in the treatment group who met the defined risk stratification requirements and who received at least one prescription for HCQ, with or without zinc, for 5 days were included in the retrospective analysis and were categorised accordingly. If the patient's electronic health record did not include information on a clinical characteristic, it was assumed that the characteristic was not present. In the group of the public reference data, only confirmed COVID-19 patients who were not treated in the respective general practice with triple therapy were included in the analysis. For this untreated control group, only outcome data for hospitalisation and all-cause death were available and used for the statistical comparison with the treatment group.

No sample size calculations were performed. Descriptive statistics are presented as median and interquartile range (IQR) for continuous variables and as frequencies (%) for categorical variables. For comparison with the results of other studies, the mean and standard deviation were calculated as needed. Normality of distribution for continuous variables was assessed by the Shapiro–Wilk test. A two-tailed Student's *t*-test was used for parametric analysis, and a Wilcoxon signed-rank test was used for non-parametric data analysis. For calculation of correlation, the point-biserial correlation coefficient was applied if one variable was dichotomous. Associations between two categorical variables were calculated with the χ^2 test. The odds ratio (OR) was calculated for comparison of the outcome of the treatment group with the untreated control group. An α value of 0.05 was considered as a significance level. Data were analysed using Microsoft Excel for Microsoft 365 MSO (32-bit), the Excel add-on Real Statistics, SigmaStat 4 and Sigma Plot 14.0.

2.7. Study approval

The study was approved by the Western Institutional Review Board and was exempt under 45 CFR § 46.104(d)(4). Ref. number: D4-Excemption-Zelenko (06-16-2020). The analysis was conducted with de-identified patient data, according to the USA Health Insurance Portability and Accountability Act (HIPAA), Safe Harbor. For that reason, exact dates and locations are not mentioned in this study.

3. Results

3.1. Patients

In accordance with available public reference data, 712 confirmed SARS-CoV-2 PCR-positive COVID-19 patients were reported for the respective community at the defined time point of the analysis. Of these 712 patients, 335 presented as outpatients at a general practice and 127 were treated with the triple combination therapy. Of these 127 patients, 104 met the risk stratification criteria and were included in the analysis (Table 1). Of the 335 patients, 208 did not meet the defined risk stratification criteria and were treated with standard of care and recovered at home. The SARS-CoV-2 infection of 37 additional patients who were clinically diagnosed with COVID-19 who met the risk stratification criteria and who were also treated with triple therapy was later confirmed by IgG tests (Table 1). These patients were included additionally in the analysis resulting in a total number of 141 patients, all with a confirmed SARS-CoV-2 infection by PCR or IgG tests. None of these patients were lost to follow-up for the defined outcome. The outcome of the remaining 377 positively tested but not treated COVID-19 patients, e.g. from other practices of the community, served as public reference (Fig. 1). Analysis of the 141 patients in the treatment group showed that all of these patients (100%) received a prescription of HCQ, 136 (96.5%) of zinc sulfate and 133 (94.3%) of azithromycin, while 1 patient (0.7%) received doxycycline instead. Instead of triple therapy, 1 patient (0.7%) in the treatment group received HCQ only, 7 patients (5.0%) received HCQ and zinc, and 4 patients (2.8%) received HCQ and azithromycin.

3.2. Baseline characteristics of the patients

Table 2 shows the baseline demographics and clinical characteristics of all 141 patients in the treatment group and for the risk stratification groups A, B and C. Of the 141 patients, 69 (48.9%) belonged to group A, 48 (34.0%) to group B and 24 (17.0%) to group C. The age ranged from 18–80 years and the median age was 58 years (IQR 40–67 years). The median age of patients in groups A, B and C was 67, 39 and 45 years, respectively. A total of 103 patients (73.0%) were male with a male-to-female ratio of 2.71. The most common co-morbidities included hypertension (28%), obesity (28%), hyperlipidaemia (23%) and diabetes mellitus (18%), whilst the least common co-morbidities were liver disease (2%), heart failure (1%) and stroke (1%). One patient (0.7%) was pregnant at initiation of treatment. There was a positive and significant correlation between age and hypertension ($r = 0.3309$, $P = 0.001$), hyperlipidaemia ($r = 0.26306$, $P < 0.001$) and cardiovascular disease ($r = 0.16757$, $P < 0.05$), whilst asthma was negatively correlated with age ($r = -0.30867$, $P < 0.001$).

The median time between onset of clinical symptoms and medical consultation was 4 days (IQR 3–6 days; available for 66/141 patients; mean 4.8 ± 2.7 days) (Table 3). There was no significant correlation between age and days from onset of clinical symptoms to consultation ($P > 0.05$). Days from onset of symptoms to consultation were not significantly different between the groups ($P > 0.05$).

The most common clinical symptoms included cough (87.2%), fever (77.3%), SOB (46.1%) and changes to or no smell or taste (30%), whilst the least common clinical symptoms were sinus congestion (16%), diarrhoea/vomiting (5%) and low back pain (3%). Table 4 shows the symptoms of all patients and stratified by groups A, B and C. There was a significant negative correlation between age and changes to smell or taste ($r = -0.43$, $P < 0.001$). No patient had a clinical diagnosis of pneumonia.

Table 5 shows the vital signs, if available, for all patients. Many patients consulted the general practice during the COVID-19 crisis

Table 1
COVID-19 diagnostics by PCR and IgG tests of patients in the treatment group

COVID-19 diagnostic [*n* (%)]	Risk-stratified group			All patients (*N* = 141)
	Group A (*N* = 69)	Group B (*N* = 48)	Group C (*N* = 24)	
SARS-CoV-2 PCR test	51 (74)	39 (81)	14 (58)	104 (74)
SARS-CoV-2 IgG test	18 (26)	9 (19)	10 (42)	37 (26)

COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Table 2
Baseline demographic and clinical characteristics of patients in the treatment group

Characteristic	Risk-stratified group			All patients (*N* = 141)
	Group A (*N* = 69)	Group B (*N* = 48)	Group C (*N* = 24)	
Age (years) [median (IQR)]	67 (64–69)	39 (24–47)	45 (36–50)	58 (40–67)
Male sex [*n* (%)]	46 (67)	40 (83)	17 (71)	103 (73)
		Co-morbidities/coexisting conditions [*n* (%)]		
Any condition	44 (64)	31 (65)	24 (100)	99 (70)
Hypertension	27 (39)	4 (8)	8 (33)	39 (28)
Hyperlipidaemia	21 (30)	7 (15)	5 (21)	33 (23)
Diabetes mellitus	16 (23)	4 (8)	5 (21)	25 (18)
Obesity[a]	20 (29)	10 (21)	10 (42)	40 (28)
Cardiovascular disease	9 (13)	1 (2)	3 (13)	13 (9)
Heart failure	2 (3)	0 (0)	0 (0)	2 (1)
Stroke	1 (2)	0 (0)	0 (0)	1 (1)
Asthma	2 (3)	9 (19)	2 (8)	13 (9)
COPD	0 (0)	0 (0)	0 (0)	0 (0)
Other lung disease	6 (9)	5 (10)	4 (17)	15 (11)
Kidney disease	1 (2)	3 (6)	2 (8)	6 (4)
Liver disease	1 (2)	2 (4)	0 (0)	3 (2)
Autoimmune disease	2 (3)	4 (8)	4 (17)	10 (7)
History of cancer	6 (9)	2 (4)	1 (4)	9 (6)
Thyroid disease	7 (10)	4 (8)	2(8)	13 (9)
Psychiatric disorder	7 (10)	4 (8)	5 (21)	16 (11)
Pregnancy	–	–	1 (4)	1 (1)

IQR, interquartile range; COPD, chronic obstructive pulmonary disease.

[a] Body mass index (BMI) ≥30 kg/m^2.

Table 3
Patients with reported days since onset of symptoms in the treatment group

Characteristic	Risk-stratified group			All patients (*N* = 141)
	Group A (*N* = 69)	Group B (*N* = 48)	Group C (*N* = 24)	
Patients with reported days [*n* (%)]	32 (46)	25 (48)	9 (38)	66 (47)
Days since onset of symptoms [median (IQR)]	4 (3–6)	3 (3–6.5)	4 (3–5.5)	4 (3–6)

IQR, interquartile range.

Table 4
COVID-19 diagnostics and baseline reported clinical symptoms of patients in the treatment group

Clinical symptom [*n* (%)]	Risk-stratified group			All patients (*N* = 141)
	Group (*N* = 69)	Group B (*N* = 48)	Group C (*N* = 24)	
Cough/dry cough	60 (87)	39 (81)	24 (100)	123 (87)
Fever	53 (77)	38 (79)	18 (75)	109 (77)
Shortness of breath	17 (25)	48 (100)	0 (0)	65 (46)
Changes to or no smell or taste	21 (30)	19 (40)	2 (8)	42 (30)
Sore throat	19 (28)	8 (17)	7 (29)	34 (24)
Headache	19 (28)	6 (13)	7 (29)	32 (23)
Runny nose/clear rhinorrhoea	16 (23)	8 (17)	4 (17)	28 (20)
Sinus congestion	10 (15)	9 (19)	4 (17)	23 (16)
Diarrhoea/vomiting	1 (2)	5 (10)	1 (4)	7 (5)
Cold symptoms	31 (45)	16 (33)	12 (50)	59 (42)
Feels sick	40 (58)	38 (79)	17 (71)	95 (67)
Weakness	44 (64)	22 (46)	11 (46)	77 (55)
Low back pain	3 (4)	0 (0)	1 (4)	4 (3)

COVID-19, coronavirus disease 2019.

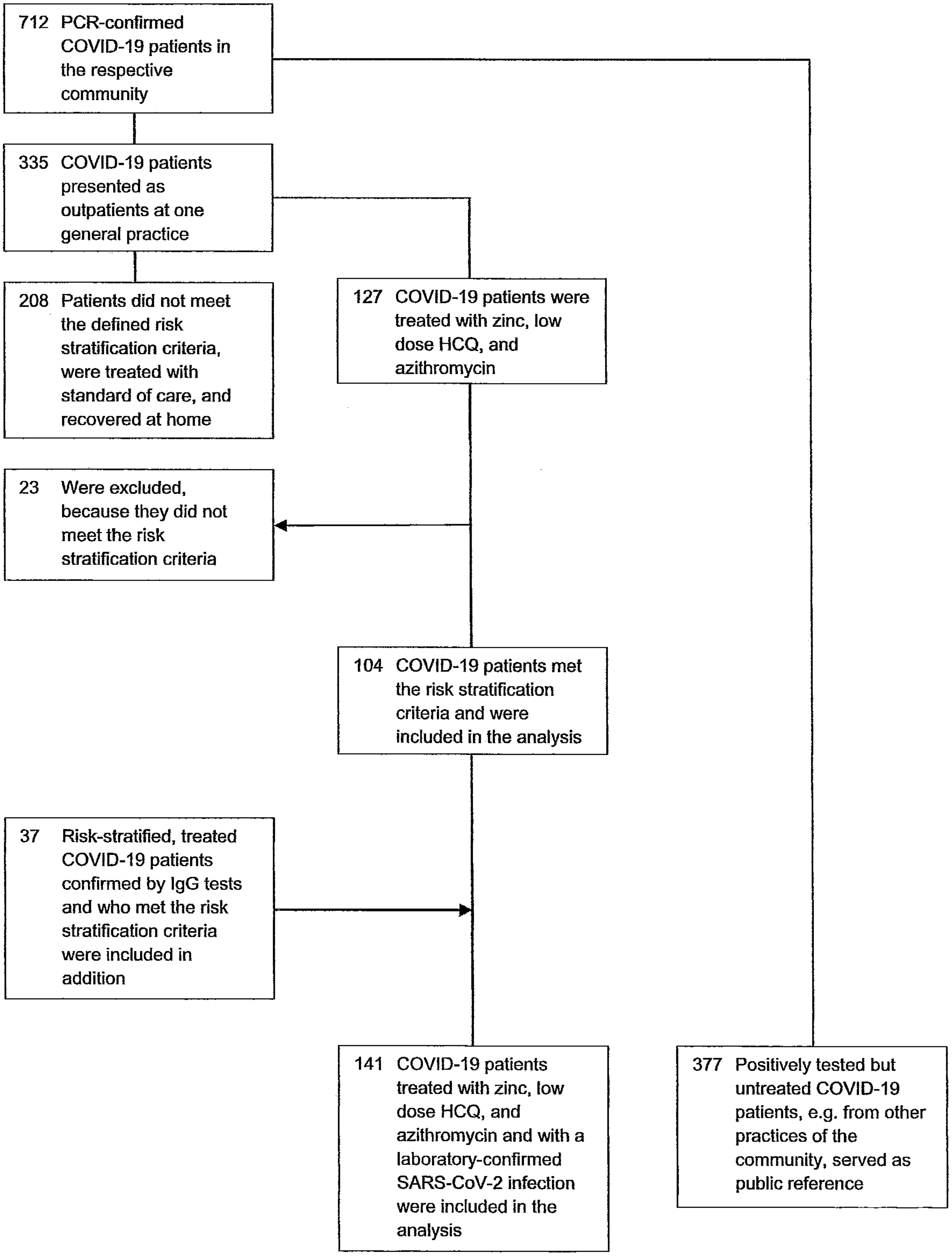

712 PCR-confirmed COVID-19 patients in the respective community
335 COVID-19 patients presented as outpatients at one general practice
208 Patients did not meet the defined risk stratification criteria, were treated with standard of care, and recovered at home
127 COVID-19 patients were treated with zinc, low dose HCQ, and azithromycin
23 Were excluded, because they did not meet the risk stratification criteria
104 COVID-19 patients met the risk stratification criteria and were included in the analysis
37 Risk-stratified, treated COVID-19 patients confirmed by IgG tests and who met the risk stratification criteria were included in addition
141 COVID-19 patients treated with zinc, low dose HCQ, and azithromycin and with a laboratory-confirmed SARS-CoV-2 infection were included in the analysis
377 Positively tested but untreated COVID-19 patients, e.g. from other practices of the community, served as public reference

Fig. 1. Study population. $N = 141$ COVID-19 patients, all with a laboratory-confirmed SARS-CoV-2 infection, were included in the analysis as the treated group. $N = 377$ positively tested COVID-19 patients of the public reference were included in the analysis as the untreated group. COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Table 5
Physical examination: vital signs of patients in the treatment group

Parameter	Median (IQR)	Patients with available parameters [*n* (%) of *N* = 141]
Heart rate (beats/min)	86 (80–94)	89 (63)
Respiratory rate (breaths/min)	16 (15–18)	43 (31)
Systolic blood pressure (mmHg)	126 (120–139)	66 (47)
Diastolic blood pressure (mmHg)	80 (74–85.5)	66 (47)
Body temperature (°C)	37.2 (37–37.8)	79 (56)
Pulse oximetry (O_2 %)	97 (96–98)	85 (60)
Body weight (kg)	88 (72.6–98.4)	43 (31)
BMI (kg/m^2)	32.2 (28.5–36.3)	30 (21)

IQR, interquartile range; BMI, body mass index.

Table 6
Co-medications of patients in the treatment group

Drug class	Patients [*n* (%) of *N* = 141]
Beta-blockers	17 (12)
Angiotensin-converting enzyme inhibitors	8 (6)
Angiotensin 2 antagonists	13 (9)
Calcium channel blockers	8 (6)
Hydrochlorothiazide	6 (4)
Statins	28 (20)
Bronchodilators	10 (7)
Antidiabetics	11 (8)
Insulin	26 (18)
Oral corticosteroids	13 (9)
Antibiotics	3 (2)

via telehealth so vital signs were not available for all of these patients. The highest proportion of patients had available measurements for heart rate (63%) and pulse oximetry (60%). Vital signs were not significantly different between risk stratification groups ($P > 0.05$) except for systolic blood pressure of groups A and B ($P < 0.05$).

Table 6 summarises the most important co-medications. Of the patients, 16% were taking angiotensin-converting enzyme inhibitors, angiotensin 2 antagonists, hydrochlorothiazide or a combination thereof. The most common long-term therapies at the time of COVID-19 diagnosis were statins (20%), beta-blockers (12%) and insulin (18%). A few patients had chronic prescriptions for oral corticosteroids (9%) for co-morbidities such as asthma or autoimmune diseases, and 3 patients (2.1%) received an additional antibiotic (levofloxacin) because of superinfections.

3.3. Hospitalisations and all-cause death

In the treatment group, 4 (2.8%) of 141 patients were hospitalised, which was significantly fewer than the 58 (15.4%) of 377 patients in the untreated group (Fig. 2) [OR = 0.16, 95% confidence interval (CI) 0.06–0.5; $P < 0.001$] (Table 7; Fig. 3). Therefore, the odds of hospitalisation of treated patients was 84% less than in the untreated patients. All hospitalised patients were male, with one in his twenties, two in their forties and one in his seventies. Three (75%) of the four hospitalised patients belonged to risk stratification group B and one (25%) to group A. All patients (100%) reported SOB at the time of consultation. The median time from onset of symptoms to consultation was 4 days. In the treatment group, one patient had to stay only 1 day in hospital, two other patients were discharged as cured and one patient died (see below). No patient was on a ventilator.

Of the 141 patients, 1 (0.7%) in treatment group A died after being hospitalised. This patient had a history of cancer and only took one daily dose of the triple therapy before hospital admission. More patients (13/377; 3.4%) died in the untreated group (Fig. 4)

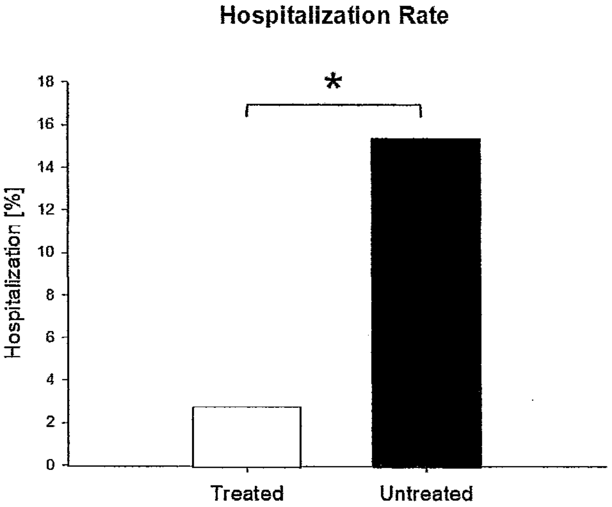


Fig. 2. Hospitalisation. Treatment with triple therapy of zinc, low-dose hydroxychloroquine and azithromycin was associated with significantly fewer hospitalisations compared with untreated patients of the public reference data. χ^2 (1, $N = 518$) = 14.17; * $P < 0.001$.

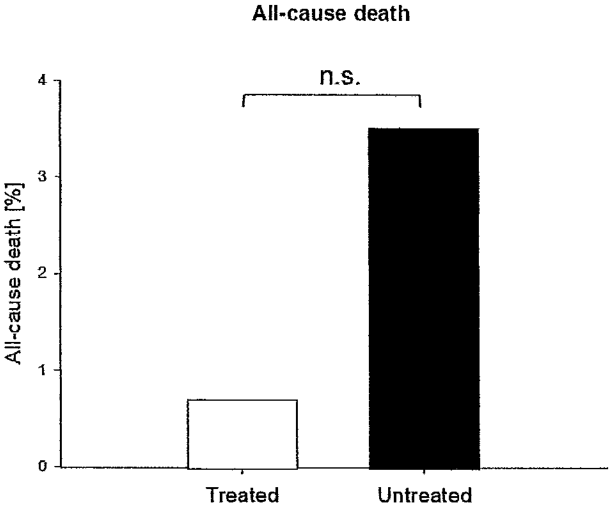
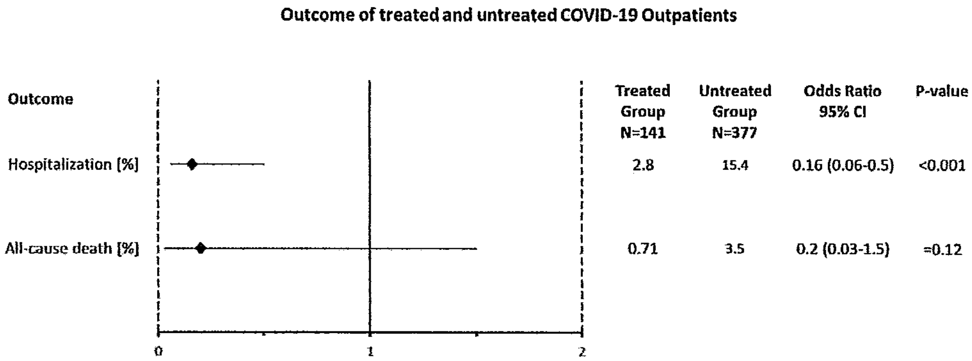


Fig. 3. All-cause deaths. Treatment with triple therapy of zinc, low-dose hydroxychloroquine and azithromycin was associated with numerically fewer all-cause deaths compared with untreated patients of the public reference data. n.s., not significant. χ^2 (1, $N = 518$) = 1.98; $P = 0.12$.

Table 7
Clinical outcomes in the treated patient group versus the untreated patient group

Outcome	Treated group [*n* (%) of *N* = 141]	Untreated group [*n* (%) of *N* = 377]	OR (95% CI)	*P*-value
Hospitalisation	4 (2.8)	58 (15.4)	0.16 (0.06–0.5)	<0.001
All-cause death	1 (0.71)	13 (3.5)	0.2 (0.03–1.5)	0.12

OR, odds ratio; CI, confidence interval.



Outcome	Treated Group N=141	Untreated Group N=377	Odds Ratio 95% CI	P-value
Hospitalization [%]	2.8	15.4	0.16 (0.06-0.5)	<0.001
All-cause death [%]	0.71	3.5	0.2 (0.03-1.5)	=0.12

Fig. 4. Odds ratios (ORs). The odds of hospitalisation in the treated patient group was 84% less than in the untreated patient group and was statistically significant ($P < 0.001$). The odds of all-cause death in the treated patient group was 80% less than in the untreated patient group but did not reach statistical significance ($P = 0.12$). COVID-19, coronavirus disease 2019; CI, confidence interval.

Table 8
Summary of adverse events in the treatment group

Event	Patients [*n* (%) of *N* = 141]
Any adverse event	67 (48)
Weakness	30 (21)
Nausea	20 (14)
Diarrhoea	15 (11)
Rash	2 (1)

(OR = 0.2, 95% CI 0.03–1.5) (Table 7; Fig. 3). Although the odds of all-cause death of treated patients was 80% less than in the untreated group, this difference did not reach statistical significance ($P = 0.12$).

All patients in the treatment group with the clinical outcome of hospitalisation or all-cause death received a prescription for the complete triple therapy including zinc, low-dose HCQ and azithromycin.

The outcome of the three different risk-stratified groups (A, B and C) was not significantly different.

The 208 patients presenting at the general practice who did not meet the risk stratification requirements and who were not treated with the triple therapy recovered at home and no hospital admissions or deaths were reported.

3.4. Safety

In general, triple therapy with zinc, low-dose HCQ and azithromycin was well tolerated. After initiation of treatment in the 141 patients, 30 (21.3%) reported weakness, 20 (14.2%) nausea, 15 (10.6%) diarrhoea and 2 (1.4%) rash (Table 8). No patient reported palpitations or any cardiac side effects.

4. Discussion

This first retrospective case series study of COVID-19 outpatients in a primary care setting showed that risk-stratified treatment early after onset of clinical symptoms with triple therapy of zinc, low-dose HCQ and azithromycin was associated with significantly fewer hospitalisations (OR = 0.16; $P < 0.001$) in comparison with untreated patients (public reference data) of the same community. Based on the performed risk stratification, the prevalences of the co-morbidities hypertension, hyperlipidaemia and diabetes mellitus were the highest in group A (>60 years and clinical symptoms), asthma and other lung diseases were the highest in group B (≤60 years and SOB), and obesity and autoimmune disease were the highest in group C (<60 years, clinical symptoms and defined co-morbidities). The most frequent symptoms of these COVID-19 patients were cough followed by fever while available median body temperature measurements were in a normal range. Almost 50% of risk-stratified and treated patients were suffering from SOB while breaths per minute and blood oxygen saturation were still in the normal range. The median time from onset of symptoms to first medical consultation was 4 days (IQR 3–6 days). Approximately 16% of patients received co-medications known to be associated with zinc deficiency, such as antihypertensive drugs. No patient experienced any known severe adverse events that were considered drug-related during treatment or follow-up.

A growing number of reports provide evidence for the effectiveness or otherwise of a range of COVID-19 drug treatments. Therefore, a living systematic review and network meta-analysis was published to assess how trustworthy the evidence is using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach [24]. Based on their most recent update from 21 July 2020, the authors conclude that glucocorticoids probably reduce mortality and mechanical ventilation in patients with COVID-19 compared with standard care. However, the effectiveness of most interventions is uncertain because most of the randomised controlled trials so far have been small and have important study limitations [24].

Another meta-analysis focused on the effectiveness of chloroquine derivatives in COVID-19 therapy [25]. The authors concluded that chloroquine derivatives are effective in improving clinical and virological outcomes and may reduce mortality by a factor of 3 in patients affected with COVID-19. They further conclude that big data are lacking basic treatment definitions and are the subject of conflict of interest [25]. At the time of this manuscript submission, only one peer-reviewed study had analysed the key health outcomes of COVID-19 patients diagnosed in a primary care setting [3]. Because of this gap in the data, the value of this study is multifold. It provides much needed recommendations for risk stratification and a treatment regimen to prevent hospitalisation and death of COVID-19 patients. The diagnosis of COVID-19 for all patients in this analysis was confirmed by PCR or IgG tests compared with a recent study in which $<3\%$ had a diagnosis confirmed by laboratory tests [26]. Starting triple therapy as early as possible after symptom onset is critical for treatment success because SARS-CoV-2 viral load appears to peak at Days 5–6 after symptom onset [27–29] and severe cases progress to ARDS after only 8–9 days [30,31]. Early antiviral treatment is an established protocol to manage severe disease progression, as was shown, for example, by a cumulative case–control study during the 2009 H1N1 influenza pandemic in Canada [32]. For patients at high risk for severe viral disease progression, it is recommended to start antiviral therapy as early as possible [33,34]. Early treatment might be also critically important to effectively reduce the SARS-CoV-2 viral load [5] and this underscores the role of early intervention by primary care physicians as reported herein.

A further strength of this approach was the simple risk stratification of symptomatic outpatients to determine the need for therapy, a strategy not yet applied in COVID-19 primary care [35] but routinely implemented in primary care for other diseases [36]. Underlying assumptions of the risk stratification used in this setting are different to other recommendations [37]. Here, age-stratified high risk was defined as >60 years (typically defined as >65 years) to encompass the common increase of co-morbidity incidences in this age group [38]. Patients ≤ 60 years with SOB, even without reduced pulse oximetry values, were treated because it was assumed the virus will likely spread from the upper to lower respiratory tract [39]. Also treated were patients ≤ 60 years with clinical symptoms and prognostically relevant co-morbidities [37]. By applying this risk stratification approach, respective care was tailored to patients with a higher likelihood for hospitalisation or fatality, which ensured that the medical principles of 'patient first' and 'doing no harm' were maintained [40]. As a result, 61.8% of COVID-19 patients were treated with standard of care only and recovered at home, and only 37.9% needed treatment with the triple therapy.

The antiviral potential of HCQ has been broadly described in vitro and in vivo [41–43]. HCQ has a long terminal elimination half-life of 32 days in plasma and 50 days in blood [44]. Therefore, the treatment approach was conservative, with the starting dose being the same as the maintenance dose and with a short treatment duration of only 5 days, being even more conservative than other recommendations [42]. HCQ-dependent intracellular increases in pH might directly interfere with pH-dependent SARS-CoV-2 replication [19]. Also, chloroquine and probably HCQ have characteristics of a zinc ionophore resulting in increasing intracellular zinc concentrations [20]. The dose of elementary zinc in this study was similar to doses previously studied to successfully prevent infections in the elderly [45]. The antiviral effects of zinc against a variety of viruses have been demonstrated during the last decades [46]. Zinc, in addition to its role as a general stimulant of antiviral immunity, is known to specifically inhibit coronavirus RNA-dependent RNA polymerase (RdRp) [21]. Based on the ionophore properties of HCQ, it has been hypothesised that zinc may enhance the efficacy of HCQ in treating COVID-19 patients [22]. In addition, zinc might inhibit the serine protease furin [47]. Furin is expressed on endothelial cells, monocytes/macrophages and smooth muscle cells in human atherosclerotic plaques [48] and therefore might play a critical role for the severe cardiovascular complications of COVID-19. As furin might be responsible to favour SARS-CoV-2 spread compared with other Betacoronaviruses [49,50] and as furin inhibition protects from certain viral-dependent infections [51], it may be important to evaluate the potential role of zinc in inhibiting this pathway.

Azithromycin was added to the treatment regimen as preliminary data provided evidence for more efficient or synergic virus elimination in conjunction with bacterial superinfection [13,52]. Although there is a synergistic antiviral effect between zinc, HCQ and azithromycin, zinc supplementation may be instrumental for the outcome of patient populations with severe clinical courses. Zinc deficiency was confirmed in a large number of healthy elderly [53] and in diabetic patients [54]. In addition, it has been documented that the antihypertensive drugs hydrochlorothiazide, angiotensin-converting enzyme inhibitors and angiotensin 2 receptor antagonists can result in increased urinary excretion of zinc with subsequent systemic zinc deficiency [55]. Age, co-morbidities and relevant co-medications align well with the majority of described COVID-19 patients at high risk, including the risk-stratified population of this analysis. Zinc deficiency might explain why certain patient groups seem not to benefit from HCQ monotherapy. During the 5-day treatment with the triple therapy and during follow-up, no severe adverse events were observed and no cases of cardiac arrhythmia were reported in this general practice, which is in accordance with available safety data for more than 300 000 patients [56].

Inherent to all retrospective analyses, our study has certain limitations, such as non-randomisation and blinding of treatment. Also, only the outcome data of the untreated control group based on the public reference were available; because no other data on patient characteristics or clinical symptoms were available, no risk adjustment was possible. Therefore, confounding factors and selection bias, among other issues, might exist. The demographic composition of the treatment group might also have had an influence on our findings. Because many physician appointments had to be managed by telehealth, vital parameters were not available for the majority of patients. Viral load and electrocardiogram (ECG) data were not analysed. Treatment with the triple therapy resulted in a numerically lower rate of all-cause death. In the absence of clinical details about the untreated patient group, the lower rate of all-cause death in the treated group was not statistically significant. However, patients in the treated group were all positively risk-stratified while the risk of the untreated group was obviously lower as this group included high- and low-risk patients. When we compared the outcome of all risk-stratified patients in the study group (treated and non-treated) with the control patients (not stratified, treated with standard therapy), hospitalisation and all-cause death were significantly less in the study group ($P < 0.0001$ and $P = 0.0154$, respectively). These data were not shown in the results section because relevant clinical information was not completely available for all patients in the control group to allow risk adjustment between groups.

In this study, the ratio of males and average age was comparable with a relevant number of other studies, but the distribution of co-morbidities was not [57]. The latter was expected because outpatients usually have a different distribution of age and especially of co-morbidities than critically ill inpatients. As expected, the prevalence of hypertension, hyperlipidaemia and cardiovascular disease correlated positively with age, while asthma correlated negatively. Approximately 50% of risk-stratified and treated patients presented with SOB, while the parameters breaths per minute and blood oxygen saturation were still within the normal range. These patients would usually not be considered for hospital admission, although SOB might be considered an alarming early sign of disease progression. Based on the implemented risk stratification, these patients were identified and treated immediately.

Indeed, three of four hospitalised patients were in risk stratification group B including patients especially with SOB, and also the hospitalised patient of group A reported SOB at the time of consultation. This supports the assumption that COVID-19 patients with SOB are at much higher risk for disease progression and need to be monitored closely.

In contrast to many other studies, the most frequent symptom was cough and not fever [58,59]. Changes in smell or taste in one-third of patients and a negative correlation with age were similar to findings from other groups [60]. While mean time from onset of symptoms to treatment was only 4.8 days (median 4 days), previously reported time spans range from 6.3 days [61] to 8 days [16], up to 16.6 days [14], or it was often even not reported [62]. In most of these studies, COVID-19 disease had most likely already progressed at the time of presentation to stages II or even stage III of the disease [6]. In many studies, often only limited information is provided about co-medications and specifically about clinical symptoms at admission [62]. The latter would be very important to better understand the differences in clinical presentation between inpatients and outpatients and thus the urgency for early anti-COVID-19 treatment in the outpatient setting [63]. The potential of zinc to enhance the antiviral efficacy of HCQ was already described in detail elsewhere [22]. This hypothesis was recently confirmed in a study using a similar triple therapy and treatment duration [23]. Zinc added to HCQ and azithromycin resulted in a significantly increased number of patients being discharged, a reduction in mortality, or transfer to hospice. In another study, when a lower dose of 200 mg of HCQ twice daily was added to basic treatment, mortality of even critically ill patients was significantly reduced [64]. These and our findings indicate that proper dosing of HCQ with its long half-life might be key for a favourable outcome of COVID-19 patients. In critical care, drugs with short half-lives are usually preferred. Especially in critically ill COVID-19 patients, higher doses of HCQ may have unforeseeable effects, e.g. on insulin sensitivity in obese patients [65] and on glucose levels in diabetics [66,67]. Besides glucose levels, it is important to closely monitor renal function, which is increasingly affected during progression of COVID-19 [68]. Because HCQ is substantially excreted by the kidneys, the risk of toxic reactions is greater in patients with impaired renal function [69].

4.1. Potential implications for clinicians and policy-makers

Clinical experience from severely ill inpatients with pneumonia who were treated with high-dose HCQ is not readily transferable to the outpatient setting with upper respiratory tract disease only. For outpatients with a median of only 4 days after onset of symptoms, COVID-19 represents a totally different disease and needs to be managed and treated differently [63]. A simple-to-perform outpatient risk stratification, as shown here, allows for rapid treatment decisions and treatment with the triple therapy of zinc, low-dose HCQ and azithromycin and may prevent a large number of hospitalisations and probably deaths during the SARS-CoV-2 pandemic. This might also help to avoid overwhelming of healthcare systems.

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Competing interests

RD is/was at the time of writing an employee of Alexion Pharma Germany GmbH, and his engagement and contribution to this study and publication was private and independent from his employer; MS is/was at the time of writing External Senior Advisor for the company LEUKOCARE (Munich, Germany) and is/was Manging Director at Starts- and -Ups Consulting (Frankfurt, Germany); VZ is/was a general practitioner in New York State (USA).

Ethical approval

This study was approved by the Western Institutional Review Board and was exempt under 45 CFR § 46.104(d)(4). Ref. Number: D4-Excemption-Zelenko (06-16-2020).

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The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 *in vitro*

Leon Caly[a], Julian D. Druce[a], Mike G. Catton[a], David A. Jans[b], Kylie M. Wagstaff[b,*]

[a] *Victorian Infectious Diseases Reference Laboratory, Royal Melbourne Hospital, At the Peter Doherty Institute for Infection and Immunity, Victoria, 3000, Australia*
[b] *Biomedicine Discovery Institute, Monash University, Clayton, Vic, 3800, Australia*

TRADUCCIÓN

El fármaco Ivermectina aprobado por la FDA inhibe la replicación de SARS-CoV-2 in Vitro.

Leon Calya, Julian D. Drucea, Mike G. Cattona, David A. Jansb, Kylie M. Wagstaffb,

- Laboratorio de Referencia de Enfermedades Infecciosas Victorian, Royal Melbourne Hospital, At the Peter Doherty Institute for Infection and Immunity, Victoria, 3000, Australia
- Biomedicine Discovery Institute, Monash University, Clayton, Vic, 3800, Australia

RESUMEN

Aunque ahora se están realizando varios ensayos clínicos para probar posibles terapias, la respuesta mundial al brote de COVID-19 se ha limitado en gran medida a la vigilancia / contención. Divulgamos aquí que la Ivermectina, un antiparasitario aprobado por la FDA que previamente demostró tener actividad antiviral de amplio espectro in vitro, es un inhibidor del virus causante (SARS-CoV-2), con una sola adición a las células Vero-HSLAM 2H después de la infección con SARS-CoV-2 capaz de efectuar una reducción de ARN viral de ~ 5000 veces a las 48 h. Por lo tanto, la Ivermectina justifica una mayor investigación sobre posibles beneficios en humanos.

Introducción

La Ivermectina es un agente antiparasitario de amplio espectro aprobado por la FDA (González Canga et al., 2008) que, en los últimos años, junto con otros grupos, hemos demostrado tener actividad antiviral contra una amplia gama de virus (Gotz et al., 2016; Lundberg et al., 2013; Tay et al., 2013; Wagstaffet al., 2012) in vitro. Originalmente identificado como un inhibidor de la interacción entre el virus de inmunodeficiencia humana-1 (VIH-1), la proteína integrasa (IN) y el heterodímero α / β1 de importina (IMP) responsable de la importación nuclear de IN (Wagstaffet al., 2011), Desde entonces, se ha confirmado que la Ivermectina inhibe la importación nuclear IN y la replicación del VIH-1 (Wagstaffet al., 2012). Se han informado otras acciones de la Ivermectina (Mastrangelo et al., 2012), pero se ha demostrado que la Ivermectina inhibe la importación nuclear del hospedador (por ejemplo, (Kosyna et al., 2015; van der Watt et al., 2016)) y proteínas virales., incluyendo la proteína no estructural 5 del virus de los simios SV40 (T-ag) y el virus del dengue (DENV) (Wagstaffet al., 2012, Wagstaffet al., 2011). Es importante destacar que se ha demostrado que limita la infección por virus de ARN como DENV 1-4 (Tayet al., 2013), West Nile Virus (Yang et al., 2020), virus de la encefalitis equina venezolana (VEEV) (Lundberg et al., 2013).) e influenza (Gotzet al., 2016), y se cree que esta actividad de amplio espectro se debe a la dependencia de muchos virus de ARN diferentes en IMPα / β1 durante la infección (Caly et al., 2012; Jans et al., 2019). De manera similar, se ha demostrado que la Ivermectina es eficaz contra el virus ADN de la pseudorrabia (PRV) tanto in vitro como in vivo, y el tratamiento con Ivermectina ha demostrado que aumenta la supervivencia en ratones infectados con PRV (Lv et al., 2018).

No se observó la eficacia de la Ivermectina contra el virus del Zika (ZIKV) en ratones, pero los autores reconocieron que las limitaciones del estudio justificaron la reevaluación de la actividad anti-ZIKV de la Ivermectina (Ketkar et al., 2019). Finalmente, la Ivermectina fue el foco de un ensayo clínico de fase III en Tailandia en 2014-2017, contra la infección por DENV, en el que se observó que una sola dosis oral diaria era segura y resultó en una reducción significativa de los niveles séricos de la proteína viralNS1, pero sin cambios en Se observó viremia o beneficio clínico (ver más abajo) (Yamasmith et al., 2018). El agente causante de la pandemia actual de COVID-19, SARS-CoV-2, es un virus de ARN de sentido positivo monocatenario que está estrechamente relacionado con severo coronavirus del síndrome respiratorio (SARS-CoV). Los estudios sobre las proteínas SARS-CoV han revelado un papel potencial de IMPα / β1 durante la infección en el cierre nucleocitoplasmático dependiente de la señal de la proteína nucleocápsida del SARS-CoV (Rowland et al., 2005; Timani et al., 2005; Wulan et al., 2015), que puede afectar la división de la célula huésped (Hiscox et al., 2001; Wurm et al., 2001). Además, se ha demostrado que la proteína accesoria de SARS-CoV ORF6 antagoniza la actividad antiviral del factor de transcripción STAT1 secuestrando IMPα / β1 en el ER rugoso / Golgimembrana (Frieman et al., 2007). En conjunto, estos informes sugirieron que la actividad inhibidora del transporte nuclear de la Ivermectina puede ser eficaz contra el SARS-CoV-2. Para probar la actividad antiviral de la Ivermectina contra el SARS-CoV-2, infectamos células Vero / HSLAM con el aislado de SARS-CoV-2 Australia / VIC01 / 2020 a una MOI de 0,1 durante 2 h, seguido de la adición de Ivermectina 5μM. El sobrenadante y los sedimentos celulares se recolectaron en los días 0 a 3 y se analizaron mediante RT-PCR para la replicación del ARN del SARS-CoV-2 (Fig. 1A / B).

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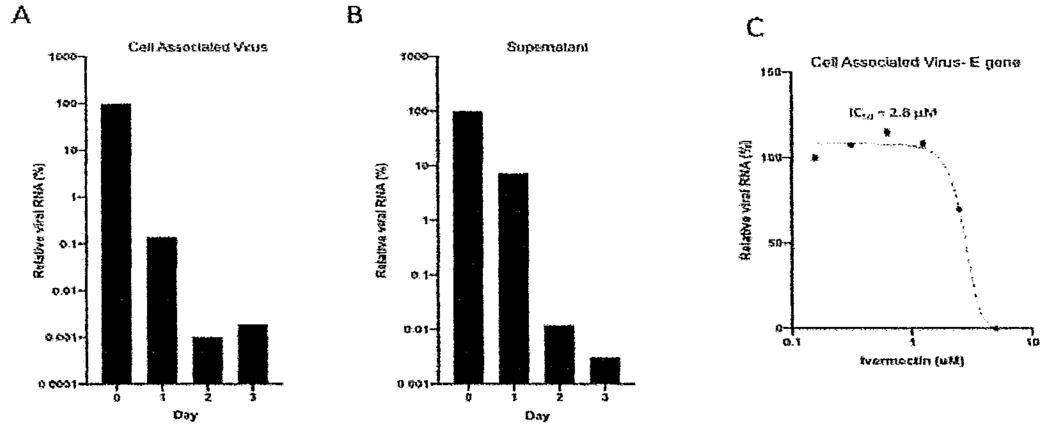

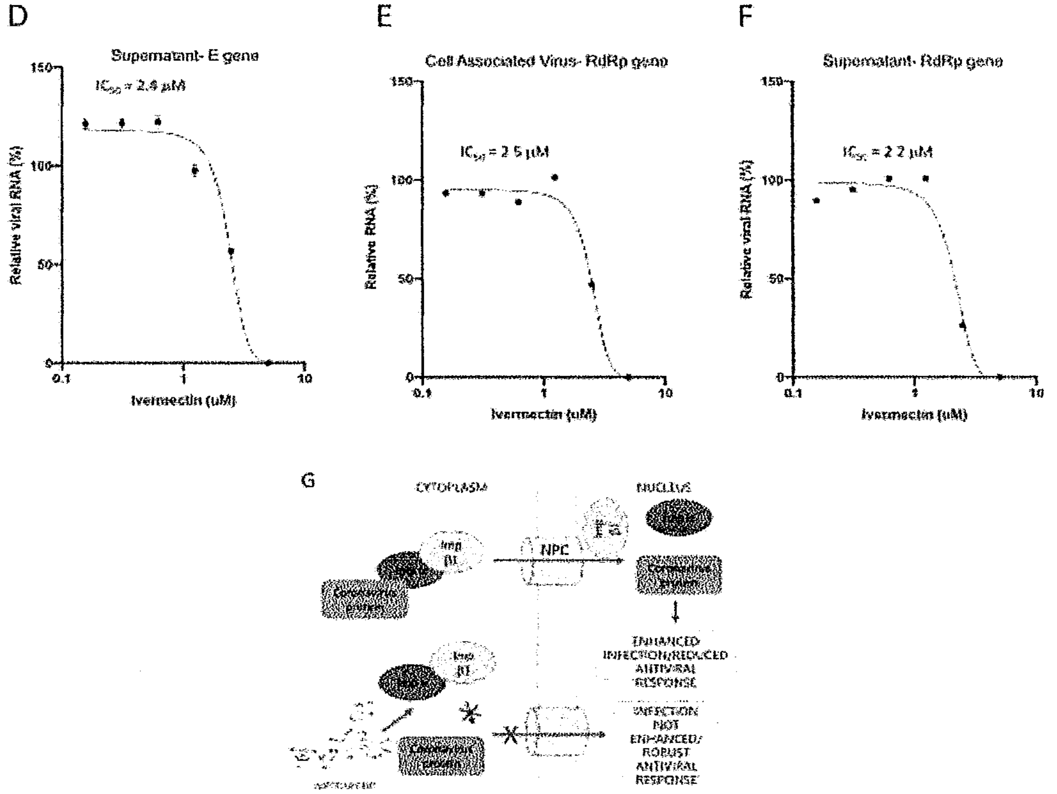

Fig. 1. La Ivermectina es un potente inhibidor del aislado clínico de SARS-CoV-2 Australia / VIC01 / 2020. Las células Vero / HSLAM se infectaron con el aislado clínico de SARS-CoV-2 Australia / VIC01 / 2020 (MOI = 0,1) durante 2 h antes de la adición de vehículo (DMSO) o Ivermectina a las concentraciones indicadas. Se tomaron muestras entre 0 y 3 días después de la infección para cuantificar la carga viral mediante PCR en tiempo real del virus asociado a células (A) o sobrenadante (B). Los valores de CI50 se determinaron en experimentos posteriores a las 48 h después de la infección usando las concentraciones indicadas de Ivermectina (tratada a las 2 h después de la infección según A / B). Se realizó un análisis de PCR en tiempo real por triplicado una vez que todos los virus asociados (C / E) o el sobrenadante (D / F) se utilizaron contra los genes SARS-CoV-2 E (C / D) o RdRp (E / F). Los resultados representan la media ± DE (n = 3). Se ajustaron las curvas de respuesta a la dosis de 3 parámetros utilizando el prisma GraphPad para determinar los valores de CI50 (indicados). G. Esquema de la acción antiviral propuesta por Ivermectina sobre el coronavirus. IMPα / β1 se une a la proteína cargo de coronavirus en el citoplasma (arriba) y la transloca a través del complejo de poros nucleares (NPC) hacia el núcleo, donde el complejo se deshace y la carga viral puede reducir la respuesta antiviral de la célula huésped, lo que conduce a una mayor infección. La Ivermectina se une al heterodímero Impα / β1 y lo desestabiliza, lo que impide que Impα / β1 se una a la proteína viral (parte inferior) y evita que entre en el núcleo. Esto probablemente da como resultado una inhibición reducida de las respuestas antivirales, lo que conduce a una respuesta antiviral normal y más eficiente.

A las 24 h, hubo una reducción del 93% en el ARN viral presente en el sobrenadante (indicativo de viriones liberados) de las muestras tratadas con Ivermectina en comparación con el vehículo DMSO. De manera similar, se observó una reducción del 99,8% en el ARN viral asociado a células (indicativo de virus no liberados y no empaquetados) con el tratamiento con Ivermectina. A las 48 h, este efecto aumentó a una reducción de ~ 5000 veces del ARN viral en las muestras tratadas con Ivermectina en comparación con las muestras de control, lo que indica que el tratamiento con Ivermectina dio como resultado la pérdida efectiva de prácticamente todo el material viral a las 48 h. De acuerdo con esta idea, no se observó ninguna reducción adicional en el ARN viral a las 72 h. Como hemos observado anteriormente (Lundberg et al., 2013; Tay et al., 2013; Wagstaffet al., 2012), no se observó toxicidad de la Ivermectina en ninguno de los puntos de tiempo probados, ni en el pozo de la muestra ni en las muestras de fármaco solo probadas en paralelo. Para determinar aún más la eficacia de la Ivermectina, las células infectadas con SARS-CoV-2 se trataron con diluciones seriadas de Ivermectina 2 Hpost infección y el sobrenadante y los sedimentos celulares recogidos para RT-PCR en tiempo real a las 48 h (Fig. 1C / D). Como anteriormente, se observó una reducción> 5000 en el ARN viral tanto en el sobrenadante como en los sedimentos celulares de las muestras tratadas con Ivermectina 5 µM a las 48 h, lo que equivale a una reducción del 99,98% en el ARN viral en estas muestras. Nuevamente, no se observó toxicidad con Ivermectina en ninguna de las concentraciones probadas. Se determinó que la CI50 del tratamiento con Ivermectina era ~ 2 µM en estas condiciones. Subrayando el hecho de que el ensayo detectó específicamente el SARS-CoV-2, los experimentos de RT-PCR se repitieron utilizando cebadores específicos para el gen RdRp viral (Fig. 1E / F) en lugar del gen E (arriba), con resultados casi idénticos observados para ambos liberados (sobrenadante) y virus asociados a células.

Tomados en conjunto, estos resultados demuestran que la Ivermectina tiene acción antiviral contra el aislado clínico de SARS-CoV-2 in vitro, con una sola dosis capaz de controlar la replicación viral dentro de las 24-48 h en nuestro sistema. Presumimos que esto probablemente se deba a la inhibición de la importación nuclear de proteínas virales mediada por IMPα / β1 (Fig. 1G), como se muestra para otros virus de ARN (Tay et al., 2013; Wagstaffet al., 2012; Yang et al., 2020); confirmación de este mecanismo en el caso del SARS-CoV-2, y la identificación del SARS-CoV-2 específico y / o componente (s) del huésped afectado (s) (ver (Yang et al., 2020)) es un factor importante. centrar el trabajo futuro en este laboratorio. En última instancia, el desarrollo de un antivírico eficaz para el SARS-CoV-2, si se administra a los pacientes al inicio de la infección, podría ayudar a limitar la carga viral, prevenir la progresión grave de la enfermedad y limitar la transmisión de persona a persona. Pruebas de evaluación comparativa de Ivermectina frente a otros antivirales potenciales para el SARS-CoV-2 con mecanismos de acción alternativos (Dong et al., 2020; Elfiky, 2020; Gordonet al., 2020; Li y De Clercq, 2020; Wang et al., 2020) sería importante tan pronto como sea posible. Este Breve Informe plantea la posibilidad de que la Ivermectina pueda ser un antiviral útil para limitar el SARS-CoV-2, de manera similar a los ya informados (Dong et al., 2020; Elfiky, 2020; Gordon et al., 2020; Li y DeClercq, 2020; Wang et al., 2020); Hasta que se demuestre que uno de estos es beneficioso en un entorno clínico, todos deben realizarse lo más rápido posible. La Ivermectina tiene un perfil de seguridad establecido para uso humano (González Canga et al., 2008; Jans et al., 2019; Buonfrate et al., 2019), y está aprobada por la FDA para una serie de infecciones parasitarias (González Canga et al., 2008; Buonfrate et al., 2019). Es importante destacar que las revisiones y los metanálisis recientes indican que la Ivermectina en dosis altas tiene una seguridad comparable con el tratamiento estándar en dosis bajas, aunque no hay suficiente evidencia para sacar conclusiones sobre el perfil de seguridad en el embarazo (Navarro et al., 2020; Nicolas et al., 2020). El siguiente paso crítico en una evaluación adicional para un posible beneficio en pacientes con COVID-19 será examinar un régimen de dosificación de adición múltiple que imite el uso actual aprobado de Ivermectina en humanos. Como se señaló, la Ivermectina fue el foco de un reciente ensayo clínico de fase III en pacientes con dengue en Tailandia, en el que se descubrió que una sola dosis diaria era segura pero no produjo ningún beneficio clínico. Sin embargo, los investigadores señalaron que se podría desarrollar un régimen de dosificación mejorado, basado en datos farmacocinéticos (Yamasmith et al., 2018). Aunque DENV es claramente muy diferente aSARS-CoV-2, el diseño de este ensayo debería informar el trabajo futuro en el futuro. En conjunto, el informe actual, combinado con un perfil de seguridad conocido, demuestra que la Ivermectina merece una consideración adicional como un posible SARS-CoV-2 antivírico.

2. Métodos

2.1. Cultivo celular, infección viral y tratamiento farmacológico

Las células Vero / HSLAM (Ono et al., 2001) se mantuvieron en Medio Esencial Mínimo (EMEM) de Earle que contenía 7% de Suero Bovino Fetal (FBS) (Bovogen Biologicals, Keilor East, AUS) 2 mM L-Glutamina, piruvato de sodio 1 mM, 1500 mg / L de bicarbonato de sodio, 15 mMHEPES y 0.4 mg / ml de genetina a 37 ° C, 5% de CO2. Las células se sembraron en placas de cultivo de tejidos de 12 pocillos 24 h antes de la infección con SARS-CoV-2 (aislado de Australia / VIC01 / 2020) a una MOI de 0,1 en los medios de infección (según los medios de mantenimiento, pero que contenían solo 2% de FBS) durante 2 h. El medio que contenía inóculo se retiró y se reemplazó con 1 ml de medio fresco (2% de FBS) que contenía Ivermectina en las concentraciones indicadas o DMSO solo y se incubó como se indica durante 0 a 3 días. En el momento apropiado, se recogió el sobrenadante celular y se centrifugó durante 10 min a 6.000 g para eliminar los desechos y el sobrenadante se transfirió a tubos de recolección nuevos. Las monocapas de células se recogieron raspando y resuspendiendo en 1 ml de medio fresco (FBS al 2%). Los controles de toxicidad se establecieron en paralelo en cada experimento en células no infectadas.

2.2. La generación de ADNc de SARS-CoV-2

se extrajo de alícuotas de 200 µl de sobrenadante de muestra o suspensión celular utilizando el kit QIAamp 96 Virus QIAcube HT (Qiagen, Hilden, Alemania) y eluyó en 60 µl. La transcripción inversa se realizó utilizando el kit de ADNc BioLine SensiFAST (Bioline, Londres, Reino Unido), mezcla de reacción total (20 µl), que contenía 10 µl de extracto de ARN, 4 µl de tampón TransAmp 5x, 1 µl de transcriptasa inversa y 5 µl de agua libre de nucleasa. Las reacciones se incubaron a 25 ° C durante 10 min, 42 ° C durante 15 min y 85 ° C durante 5 min.

2.3. Detección de SARS-CoV-2 mediante un ensayo de RT-PCR en tiempo real

TaqMan El ensayo de RT-PCR de TaqMan se realizó utilizando 2,5 µl de cDNA, 10 µl de diseño de primario Precisión PLUS qPCR Master Mix 1 µM Forward (5'- AAATTC TAT GGT GGT TGG CAC AAC ATG TT- 3 '), cebadores inversos de 1 µM (5'- TAGGCA TAG CTC TRT CAC AYT T-3 ') y sonda de 0,2 µM (5'-FAM-TGG GTT GGG ATT ATC-MGBNFQ-3 ') dirigidos a BetaCoV RdRp (RNA- ARN polimerasa

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dependiente) o Forward (5'-ACA GGT ACG TTA ATA GTT AAT AGC GT -3 '), cebadores inversos 1µM (5'-ATA TTG CAG CAGTAC GCA CAC A-3 ') y sonda 0,2µM (5'-FAM-ACA CTA GCCATC CTT ACT GCG CTT CG-286 NFQ -3 ') que se dirige al gen BetaCoV E (Corman et al., 2020). Los ensayos de RT-PCR en tiempo real se realizaron en una máquina de PCR en tiempo real Applied Biosystems ABI 7500 Fast (Applied Biosystems, Foster City, CA, EE. UU.) Utilizando condiciones de ciclo de 95 ° C durante 2 min, 95 ° C durante 5 s, 60 ° C durante 24 s. Se usó ADNc de SARS-CoV-2 (Ct ~ 28) como control positivo. Los valores de Ct calculados se convirtieron en una reducción de veces de las muestras tratadas en comparación con el control usando el método methodCt (veces cambiado en el ARN viral = 2 ^ ΔCt) y se expresaron como% de DMSO sola muestra. Los valores de CI50 se ajustaron utilizando curvas de respuesta a la dosis de 3 parámetros en el prisma GraphPad.

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Camera dei deputati
Lo que calla
la TV

"Hemos disparado sobre los pulmones, los hemos oxidado, los hemos quemado.
HEMOS MATADO A LAS PERSONAS"

Dr. Bacco en la cámara de diputados de Italia: «Los enfermos no murieron por el virus, sino por los tratamientos»

14 de agosto de 2020

En su intervención en la Cámara de Diputados de Italia, como parte de la conferencia "Coronavirus: ¿emergencia sanitaria o democracia?" que tuvo lugar en Roma el martes 28 de julio de 2020, el doctor Pasquale Mario Bacco explica cómo los ancianos enfermos de Covid-19 murieron por culpa de los tratamientos y no del virus, y afirma que no existen los enfermos asintomáticos.

Publicidad

Pasquale Mario Bacco asistió al Liceo Científico E. Medi y estudió medicina y cirugía en Nápoles, Italia. Actualmente es médico e investigador en Medicina Lavoro y Ambiente (Meleam), una sociedad anónima que desde 1998 ofrece diferentes tipos de servicios a sus clientes con el objetivo de ofrecer soluciones que les permitan trabajar de forma segura y serena.

Grabación en vídeo de la conferencia de prensa titulada "Coronavirus: ¿emergencia sanitaria o democracia?" que tuvo lugar en Roma el martes 28 de julio de 2020 a las 10:00 a.m.

Con Sara Cunial (diputada, Mixta), Giulio Tarro (medco, fundador de la Asociación L'Eretico), Angelo Giorgianni (magistrado), Pasquale Mario Bacco (médico).

Publicidad

Los conferencistas expone cómo desde el comienzo de la llamada emergencia del Coronavirus, muchos científicos han puesto de relieve una serie de cuestiones críticas de carácter médico-científico, epidemiológico y jurídico.

Enfoques diagnósticos erróneos, tratamiento inapropiado, contención imprudente del contagio y medidas de seguridad que siguen vigentes hoy en día.

La conferencia de prensa fue organizada por la Associazione L'Eretico.

En la conferencia se discutieron los siguientes temas: Avión, Ancianos, Censura, China, Comercio, Conde, Tribunal Constitucional, Constitución, Decretos, Democracia, Ley, Emergencia, Epidemias, Europa, Gobierno, Infancia, Enfermeras, Información, Instituciones, Italia, Derecho, Lombardía, Médicos, Medicina, Oms, Hospitales, Polémica, Política, Prevención, Regiones, Investigación, Salud, Sanidad, Ciencia, Seguridad, Sociedad, España, Estadística, Estado, Transporte, Unión Europea, Vacunas.

La grabación en vídeo de la conferencia de prensa dura 1 hora y 4 minutos y puede verse completa en italiano en Radio Radicale.

https://trikooba.com/2020/08/14/dr-bacco-en-la-camara-de-diputados-de-italia-los-enfermos-no-murieron-por-el-virus-sino-por-los-tratamientos/

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Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial

Philippe Gautret,[a,b,$] Jean-Christophe Lagier,[a,c,$] Philippe Parola,[a,b] Van Thuan Hoang,[a,b,d] Line Meddeb,[a] Morgane Mailhe,[a] Barbara Doudier,[a] Johan Courjon,[e,f,g] Valérie Giordanengo,[h] Vera Esteves Vieira,[a] Hervé Tissot Dupont,[a,c] Stéphane Honoré,[i,j] Philippe Colson,[a,c] Eric Chabrière,[a,c] Bernard La Scola,[a,c] Jean-Marc Rolain,[a,c] Philippe Brouqui,[a,c] and Didier Raoult[a,c,*]

[a]IHU-Méditerranée Infection, Marseille, France
[b]Aix Marseille Univ, IRD, AP-HM, SSA, VITROME, Marseille, France
[c]Aix Marseille Univ, IRD, APHM, MEPHI, Marseille, France
[d]Thai Binh University of Medicine and Pharmacy, Thai Binh, Viet Nam
[e]Infectiologie, Hôpital de l'Archet, Centre Hospitalier Universitaire de Nice, Nice, France
[f]Université Côte d'Azur, Nice, France
[g]U1065, Centre Méditerranéen de Médecine Moléculaire, C3M, Virulence Microbienne et Signalisation Inflammatoire, INSERM, Nice, France
[h]Department of Virology, Biological and Pathological Center, Centre Hospitalier Universitaire de Nice, 06200 Nice, France
[i]Service Pharmacie, Hôpital Timone, AP-HM, Marseille, France
[j]Laboratoire de Pharmacie Clinique, Aix Marseille Université, Marseille, France
Didier Raoult: Didier.raoult@gmail.com
*Corresponding author. Didier.raoult@gmail.com
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Abstract

Background

Chloroquine and hydroxychloroquine have been found to be efficient on SARS-CoV-2, and reported to be efficient in Chinese COV-19 patients. We evaluate the effect of hydroxychloroquine on respiratory viral loads.

Patients and methods

French Confirmed COVID-19 patients were included in a single arm protocol from early March to March 16th, to receive 600mg of hydroxychloroquine daily and their viral load in nasopharyngeal swabs was tested daily in a hospital setting. Depending on their clinical presentation, azithromycin was added to the treatment. Untreated patients from another center and cases refusing the protocol were included as negative controls. Presence and absence of virus at Day6-post inclusion was considered the end point.

Results

Six patients were asymptomatic, 22 had upper respiratory tract infection symptoms and eight had lower respiratory tract infection symptoms.

Twenty cases were treated in this study and showed a significant reduction of the viral carriage at D6-post inclusion compared to controls, and much lower average carrying duration than reported in the litterature for untreated patients. Azithromycin added to hydroxychloroquine was significantly more efficient for virus elimination.

Conclusion

Despite its small sample size, our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin.

Key words: 2019-nCoV, SARS-CoV-2, COVID-19, Hydroxychloroquine, Azithromycin, Clinical trial

1. Introduction

In late December 2019, an outbreak of an emerging disease (COVID-19) due to a novel coronavirus (later named SARS-CoV-2) started in Wuhan, China and rapidly spread in China and outside [1,2]. The WHO declared the epidemic of COVID-19 as a pandemic on March 12th 2020 [3]. According to a recent Chinese study, about 80% of patients present with mild disease and the overall case-fatality rate is about 2.3% but reaches 8.0% in patients aged 70 to 79 years and 14.8% in those aged ≥80 years [4]. However, there is probably an important number of asymptomatic carriers in the population, and thus the mortality rate is probably overestimated. France is now facing the COVID-19 wave with more than 4500 cases, as of March 14th 2020 [5]. Thus, there is an urgent need for an effective treatment to treat symptomatic patients but also to decrease the duration of virus carriage in order to limit the transmission in the community. Among candidate drugs to treat COVID-19, repositioning of old drugs for use as antiviral treatment is an interesting strategy because knowledge on safety profile, side effects, posology and drug interactions are well known [6,7].

A recent paper reported an inhibitor effect of remdesivir (a new antiviral drug) and chloroquine (an old antimalarial drug) on the growth of SARS-CoV-2 *in vitro,* [8] and an early clinical trial conducted in Chinese COVID-19 patients, showed that chloroquine had a significant effect, both in terms of clinical outcome and viral clearance, when compared to controls groups [9,10]. Chinese experts recommend that patients diagnosed with mild, moderate and severe cases of COVID-19 pneumonia and without contraindications to chloroquine, be treated with 500 mg chloroquine twice a day for ten days [11].

Hydroxychloroquine (an analogue of chloroquine) has been demonstrated to have an anti-SARS-CoV activity *in vitro* [12]. Hydroxychloroquine clinical safety profile is better than that of chloroquine (during long-term use) and allows a higher daily dose [13] and has fewer concerns regarding drug-drug interactions [14]. Our team has a very comprehensive experience (over 20 years) in successfully treating patients with chronic diseases due to intracellular bacteria (Q fever due to *Coxiella burnetii* and Whipple's disease due to *Tropheryma whipplei*) with long-term hydroxychloroquine treatment (600 mg/day for 12 to 18 months) [15,16]. We therefore started to conduct a clinical trial aiming at assessing the effect of hydroxychloroquine on SARS-CoV-2-infected patients after approval by the French Ministry of Health. In this report we describe our early results, focusing on virological data in patients receiving hydroxychloroquine as compared to a control group.

2. Study population and Methods

2.1. Setting

This ongoing study is coordinated by The Méditerranée Infection University Hospital Institute in Marseille. Patients who were proposed a treatment with hydroxychloroquine were recruited and managed in the Marseille centre. Controls without hydroxychloroquine treatment were recruited in Marseille, Nice, Avignon and Briançon centers, all located in Southern France.

2.2. Patients

Hospitalized patients with confirmed COVID-19 were included in this study if they fulfilled two primary criteria: i) age >12 years; ii) PCR documented SARS-CoV-2 carriage in nasopharyngeal sample at admission regardless of their clinical status.

Patients were excluded if they had a known allergy to hydroxychloroquine or chloroquine or had another known contraindication to treatment with the study drug, including retinopathy, G6PD deficiency and QT prolongation. Breastfeeding and pregnant patients were excluded based on their declaration and pregnancy test results when required.

2.3. Informed consent

Before being included in the study, patients meeting inclusion criteria had to give their consent to participate to the study. Written informed signed consent was obtained from adult participants (≥ 18 years) or from parents or legal guardians for minors (<18 years). An information document that clearly indicates the risks and benefits associated with the participation to the study was given to each patient. Patients received information about their clinical status during care regardless of whether they participate in the study or not. Regarding patient identification, a study number was assigned sequentially to included participants, according to the range of patient numbers allocated to each study centre. The study was conducted in accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines of good clinical practice, the Helsinki Declaration, and applicable standard operating procedures.

The protocol, appendices and any other relevant documentation were submitted to the French National Agency for Drug Safety (ANSM) (2020-000890-25) and to the French Ethic Committee (CPP Ile de France) (20.02.28.99113) for reviewing and were approved on 5th and 6th March, 2020, respectively.

This trial is registered in EU Clinical Trials Register with number 2020-000890-25.

2.4. Procedure

Patients were seen at baseline for enrollment, initial data collection and treatment at day-0, and again for daily follow-up during a 14 day period. Each day, patients received a standardized clinical examination and when possible, a nasopharyngeal sample was collected. All clinical data were collected using standardized questionnaires. All patients in the Marseille center were proposed oral hydroxychloroquine sulfate 200 mg, three times per day for ten days (in this preliminary phase, we did not enroll children in the treatment group based on data indicating that children develop mild symptoms of COVID-19 [4]). Patients who refused the treatment or had an exclusion criteria, served as controls in the Marseille centre. Patients in other centers did not receive hydroxychloroquine and served as controls. Symptomatic treatment and antibiotics as a measure to prevent bacterial super-infection was provided by investigators based on clinical judgment. Hydroxychloroquine was provided by the National Pharmacy of France on nominative demand.

2.5. Clinical classification

Patients were grouped into three categories: asymptomatic, upper respiratory tract infection (URTI) when presenting with rhinitis, pharyngitis, or isolated low-grade fever and myalgia, and lower respiratory tract infections (LRTI) when presenting with symptoms of pneumonia or bronchitis.

2.6. PCR assay

SARS-CoV-2 RNA was assessed by real-time reverse transcription-PCR [17].

2.7. Hydroxychloroquine dosage

Native hydroxychloroquine has been dosed from patients' serum samples by UHPLC-UV using a previously described protocol [18]. The peak of the chromatogram at a retention time of 1.05 min corresponds to hydroxychloroquine metabolite. The serum concentration of this metabolite is deduced from UV absorption, as for hydroxychloroquine concentration. Considering both concentrations provides an estimate of initial serum hydroxychloroquine concentration.

2.8. Culture

For all patients, 500 µL of the liquid collected from the nasopharyngeal swab were passed through a 0.22-µm pore sized centrifugal filter (Merck millipore, Darmstadt, Germany), then were inoculated in wells of 96-well culture microplates, of which 4 wells contained Vero E6 cells (ATCC CRL-1586) in Minimum Essential Medium culture medium with 4% fetal calf serum and 1% glutamine. After centrifigation at 4,000 g, the microplates were incubated at 37°C. Plates were observed daily for evidence of cytopathogenic effect. Presumptive detection of the virus in the supernatant was done using SU5000 SEM (Hitachi) then confirmed by specific RT-PCR.

2.9. Outcome

The primary endpoint was virological clearance at day-6 post-inclusion. Secondary outcomes were virological clearance over the time of the study period and clinical follow-up (body temperature, respiratory rate, lenght of stay in hospital and mortality), and occurrence of side-effects.

2.10. Statistics

Assuming a 50% efficacy of hydroxychloroquine in reducing the viral load at day 7, an 85% power, a type I error rate of 5% and 10% loss to follow-up, we calculated that a total of 48 COVID-19 patients (ie, 24 cases in the hydroxychloroquine group and 24 in the control group) would be required for the analysis (Fleiss with CC). Statistical differences were evaluated by Pearson's chi-square or Fisher's exact tests as categorical variables, as appropriate. Means of quantitative data were compared using Student's t-test. Analyses were performed in Stata version 14.2.

4. Discussion

For ethical reasons and because our first results are so significant and evident we decided to share our findings with the medical community, given the urgent need for an effective drug against SARS-CoV-2 in the current pandemic context.

We show here that hydroxychloroquine is efficient in clearing viral nasopharyngeal carriage of SARS-CoV-2 in COVID-19 patients in only three to six days, in most patients. A significant difference was observed between hydroxychloroquine-treated patients and controls starting even from day3 post-inclusion. These results are of great importance because a recent paper has shown that the mean duration of viral shedding in patients suffering from COVID-19 in China was 20 days (up to 37 days for the longest duration) [19]

Very recently, a Chinese team published results of a study demonstrating that chloroquine and hydroxychloroquine inhibit SARS-CoV-2 *in vitro* with hydroxychloroquine (EC50=0.72%μM) found to be more potent than chloroquine (EC50=5.47%μM) [14]. These *in vitro* results corroborate our clinical results. The target values indicated in this paper [14] were reached in our experiments. The safer dose-dependent toxicity profile of hydroxychloroquine in humans, compared to that of chloroquine [13], allows using clinical doses of hydroxychloroquine that will be over its EC50 observed *in vitro* [14].

Our preliminary results also suggest a synergistic effect of the combination of hydroxychloroquine and azithromycin. Azithromycin has been shown to be active *in vitro* against Zika and Ebola viruses [20], [21], [22] and to prevent severe respiratory tract infections when administrated to patients suffering from viral infection [23]. This finding should be further explored to know whether a combination is more effective especially in severe cases. Speculated potential risk of severe QT prolongation induced by the association of the two drugs has not been established yet but should be considered. As for each treatment, the cost benefits of the risk should be evaluated individually. Further studies on this combination are needed, since such combination may both act as an antiviral therapy against SARS-CoV-2 and prevent bacterial super-infections.

The cause for a failure of hydroxychloroquine treatment should be investigated by testing the isolated SARS-CoV-2 strains of the non-respondents and analyzing their genome, and by analyzing the host factors that may be associated with the metabolism of hydroxychloroquine. The existence of hydroxychloroquine failure in two patients (mother and son) is more suggestive of the last mechanism of resistance.

Such results are promising and open the possibility of an international strategy to decision-makers to fight this emerging viral infection in real-time even if other strategies and research including vaccine development could be also effective, but only in the future. We therefore recommend that COVID-19 patients be treated with hydroxychloroquine and azithromycin to cure their infection and to limit the transmission of the virus to other people in order to curb the spread of COVID-19 in the world. Further works are also warranted to determine if these compounds could be useful as chemoprophylaxis to prevent the transmission of the virus, especially for healthcare workers. Our study has some limitations including a small sample size, limited long-term outcome follow-up, and dropout of six patients from the study, however in the current context, we believe that our results should be shared with the scientific community.

3. Results (detailed results are available in supplementary Table 1)

3.1. Demographics and clinical presentation

We enrolled 36 out of 42 patients meeting the inclusion criteria in this study that had at least six days of follow-up at the time of the present analysis. A total of 26 patients received hydroxychloroquine and 16 were control patients. Six hydroxychloroquine-treated patients were lost during the follow-up of the survey because of early cessation of treatment. Reasons are as follows: three patients were transferred to intensive care unit, including one transferred on day2 post-inclusion who was PCR-positive on day1, one transferred on day3 post-inclusion who was PCR-positive on days1-2 and one transferred on day4 post-inclusion who was PCR-positive on day1 and day3; one patient died on day3 post inclusion and was PCR-negative on day2; one patient decided to leave the hospital on day3 post-inclusion and was PCR-negative on days1-2; finally, one patient stopped the treatment on day3 post-inclusion because of nausea and was PCR-positive on days1-2-3. The results presented here are therefore those of 36 patients (20 hydroxychloroquine-treated patients and 16 control patients). None of the control patients were lost during follow-up. Basic demographics and clinical status are presented in Table 1 . Overall, 15 patients were male (41.7%), with a mean age of 45.1 years. The proportion of asymptomatic patients was 16.7%, that of patients with URTI symptoms was 61.1% and that of patients with LRTI symptoms was 22.2%. All patients with LRTI symptoms had confirmed pneumonia by CTScan. Hydroxychloroquine-treated patients were older than control patients (51.2 years vs. 37.3 years). No significant difference was observed between hydroxychloroquine-treated patients and control patients with regard to gender, clinical status and duration of symptoms prior to inclusion (Table 1). Among hydroxychloroquine-treated patients six patients received azithromycin (500mg on day1 followed by 250mg per day for the next four days) to prevent bacterial super-infection and were kept under daily electrocardiogram control. Clinical follow-up and occurrence of side-effects will be described in a further paper at the end of the trial.

Table 1

Characteristics of the study population.

	Age (years)			Male gender		Clinical status				Time bet of sympt inclusion	
	Mean ± SD	**t**	**p-value**	**n (%)**	**p-value**	**Asymptomatic**	**URTI**	**LRTI**	**p-value**	**Mean ± SD**	
Hydroxychloroquine treated patients (N=20)	51.2 ± 18.7	-1.95	0.06	9 (45.0)	0.65	2 (10.0)	12 (60.0)	6 (30.0)	0.30	4.1 ± 2.6	-(
Control patients (N=16)	37.3 ± 24.0			6 (37.5)		4 (25.0)	10 (62.5)	2 (12.5)		3.9 ± 2.8	
All patients (36)	45.1 ± 22.0			15 (41.7)		6 (16.7)	22 (61.1)	8 (22.2)		4.0 ± 2.6	

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URTI: upper tract respiratory infection, LRTI: lower tract respiratory infection

3.2. Hydroxychloroquine dosage

Mean hydroxychloroquine serum concentration was 0.46 µg/ml±0.2 (N=20).

3.3. Effect of hydroxychloroquine on viral load

The proportion of patients that had negative PCR results in nasopharyngeal samples significantly differed between treated patients and controls at days 3-4-5 and 6 post-inclusion (Table 2). At day6 post-inclusion, 70% of hydroxychloroquine-treated patients were virologically cured compared to 12.5% in the control group (p= 0.001).

Table 2

Proportion of patients with virological cure (negative nasopharyngeal PCR) by day, in COVID-19 patients treated with hydroxychloroquine and in COVID-19 control patients.

	Day3 post inclusion			**Day4 post inclusion**			**Day5 post inclusion**		
	Number of negative patients/total number of patients	**%**	**p-value**	**Number of negative patients/total number of patients**	**%**	**p-value**	**Number of negative patients/total number of patients**	**%**	**p-value**
Hydroxychloroquine treated patients (N=20)	10/20	50.0	0.005	12/20	60.0	0.04	13/20	65.0	0.006
Control patients (N=16)	1/16	6.3		4/16	25.0		3/16	18.8	

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[a]control patients from centers other than Marseille did not undergo daily sampling, but were sampled every other day in most cases, they were considered positive for PCR when actually positive the day(s) before and the day(s) after the day(s) with missing data.

When comparing the effect of hydroxychloroquine treatment as a single drug and the effect of hydroxychloroquine and azithromycin in combination, the proportion of patients that had negative PCR results in nasopharyngeal samples was significantly different between the two groups at days 3-4-5 and 6 post-inclusion (Table 3). At day6 post-inclusion, 100% of patients treated with a combination of hydroxychloroquine and azithromycin were virologically cured compared to 57.1% of patients treated with hydroxychloroquine only, and 12.5% in the control group ($p<0.001$). These results are summarized in Fig. 1, Fig. 2 . Drug effect was significantly higher in patients with symptoms of URTI and LRTI, as compared to asymptomatic patients with $p<0.05$ (data not shown).

Table 3

Proportion of patients with virological cure (negative nasopharyngeal PCR) by day, in COVID-19 patients treated with hydroxychloroquine only, in COVID-19 patients treated with hydroxychloroquine and azithromycin combination, and in COVID-19 control patients.

	Day3 post inclusion			**Day4 post inclusion**			**Day5 post inclusion**		
	Number of negative patients/total number of patients	**%**	**p-value**	**Number of negative patients/total number of patients**	**%**	**p-value**	**Number of negative patients/total number of patients**	**%**	**p-value**
Control patients	1/16	6.3	0.002	4/16	25.0	0.05	3/16	18.8	0.002
Hydroxychloroquine treatment only	5/14	35.7		7/14	50.0		7/14	50.0	
Hydroxychloroquine and azithromycin combined treatment	5/6	83.3		5/6	83.3		6/6	100	

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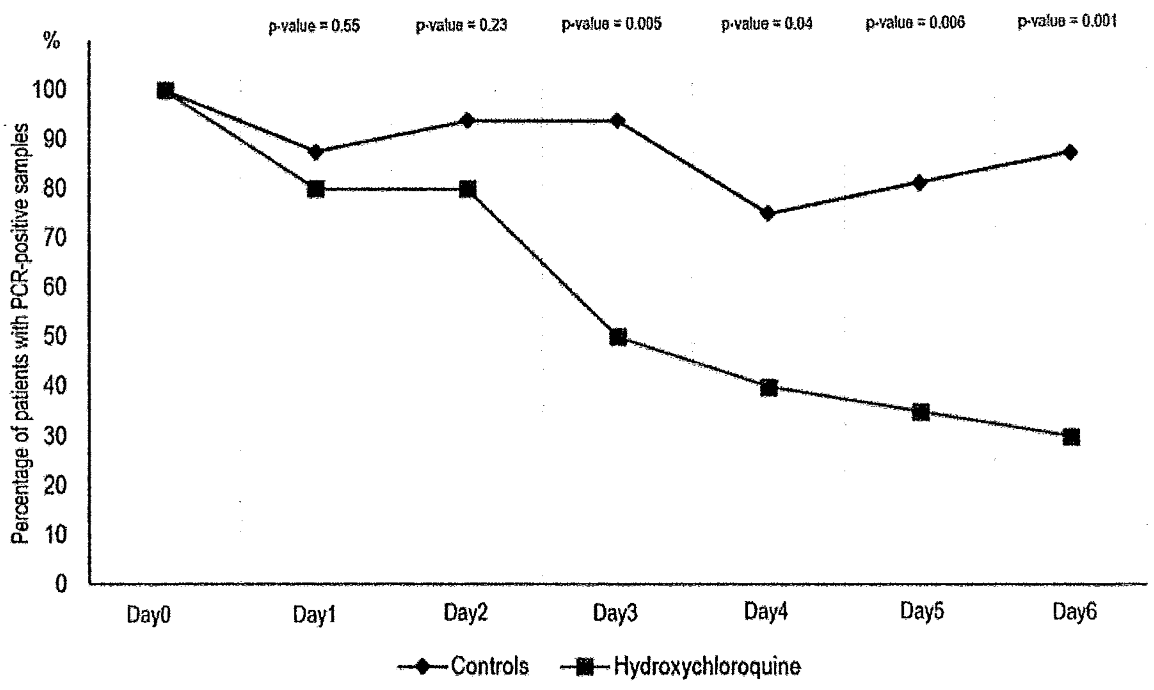

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Fig. 1

Percentage of patients with PCR-positive nasopharyngeal samples from inclusion to day6 post-inclusion in COVID-19 patients treated with hydroxychloroquine and in COVID-19 control patients.

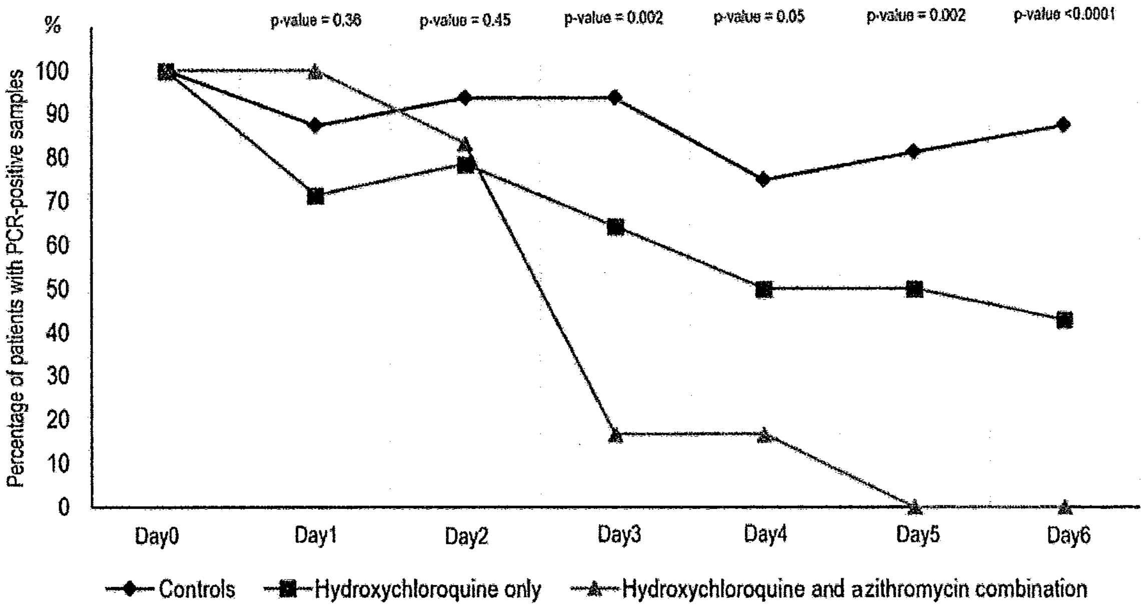

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Fig. 2

Percentage of patients with PCR-positive nasopharyngeal samples from inclusion to day6 post-inclusion in COVID-19 patients treated with hydroxychloroquine only, in COVID-19 patients treated with hydroxychloroquine and azithromycin combination, and in COVID-19 control patients.

Of note, one patient who was still PCR-positive at day6-post inclusion under hydroxychloroquine treatment only, received azithromycin in addition to hydroxychloroquine at day8-post inclusion and cured her infection at day-9 post inclusion. In contrast, one of the patients under hydroxychloroquine and azithromycin combination who tested negative at day6 post-inclusion was tested positive at low titer at day8 post-inclusion.

3.4. Cultures

We could isolate SARS-CoV-2 in 19 out of 25 clinical samples from patients.

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Declarations

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Competing Interests: None declared.

Ethical Approval: French Ethic Committee (CPP Ile de France) (20.02.28.99113).

Notes

Editor: Dr. Po-Ren Hsueh

Footnotes

Given his role as Editor in Chief of this journal, Jean Marc Rolain had no involvement in the peer-review of this article and has no access to information regarding its peer-review. Full responsibility for the peer-review process for this article was delegated to P.R. Hsueh.

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijantimicag.2020.105949.

Appendix. Supplementary material

Click here to view.(77K, pdf)Image, application 1

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U.S. Department of Justice

Request for Expedited Federal Investigation Into Scientific Fraud in Public Health Policies

We are writing this letter to request that a federal investigation be commenced and/or expedited regarding the scientific debate on major policy decisions during the COVID-19 crisis. In the course of our work, we have identified issues of a potentially criminal nature and believe this investigation necessary to ensure the interests of the public have been properly represented by those promoting certain pandemic policies.

During times of crisis, citizens naturally turn to the advice of those they perceive as experts. In early 2020, the public turned to the advice of scientific authorities when confronted with an apparent viral outbreak. Soon after, most nations followed the advice of prominent scientists and implemented restrictions commonly referred to as "lockdowns." While the policies varied by jurisdiction, in general they involved restrictions on gatherings and movements and the closure of schools, businesses, and public places, inspired by those imposed by the Chinese Communist Party (CCP) in Hubei Province. The intervention of federal authorities with police power may be required to ensure that those who have promoted these lockdown policies have done so in good faith.

This letter is meant to call the attention of federal authorities in Australia, Canada, Germany, the United Kingdom, and the United States (the "Nations") to multiple points of evidence about the origin and historical precedent of lockdowns; the scientific literature and debate behind them; the provenance and quality of predominant COVID-19 testing protocols and models; the motivations, biases, and qualifications of certain prominent lockdown supporters; and the source of public-facing communications surrounding these policies.

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1. Lockdowns Originated on the Order of Xi Jinping, General Secretary of the Chinese Communist Party, and Were Propagated Into Global Policy by the World Health Organization With Little Analysis or Logic

Lockdown proponents have frequently justified their policies by comparing them to actions taken to combat the pandemic of Spanish influenza a century prior.[1] But a realistic examination of the mitigation efforts in response to Spanish influenza reveals that nothing remotely approximating lockdowns was ever imposed. In the words of Judge William S. Stickman, ruling in *Cnty. of Butler v. Wolf*,[2] citing the work of preeminent historians:

> Although this nation [the United States] has faced many epidemics and pandemics and state and local governments have employed a variety of interventions in response, there have never previously been lockdowns of entire populations—much less for lengthy and indefinite periods of time...[3] While, unquestionably, states and local governments restricted certain activities for a limited period of time to mitigate the Spanish Flu, there is no record of any imposition of a population lockdown in response to that disease or any other in our history.

Not only are lockdowns historically unprecedented in response to any previous epidemic or pandemic in American history, but they are not so much as mentioned in recent guidance offered by the U.S. Centers for Disease Control and Prevention ("CDC"). Judge Stickman continues:

> Indeed, even for a 'Very High Severity' pandemic (defined as one comparable to the Spanish Flu), the guidelines provide only that 'CDC recommends *voluntary* home isolation of ill persons,' and 'CDC might recommend *voluntary* home quarantine of exposed household members in areas where novel influenza circulates.' *Id.* at 32, Table 10 (emphasis added). This is a far, far cry from a statewide lockdown...[4]

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[1] *E.g.*, Emily Badger and Quoctrung Bui, *Cities That Went All In on Social Distancing in 1918 Emerged Stronger for It*, N.Y. Times, Apr. 3, 2020, https://www.nytimes.com/interactive/2020/04/03/upshot/coronavirus-cities-social-distancing-better-employment.html.

[2] Civil Action No. 2:20-cv-677 (W.D. Pa. May. 28, 2020), https://casetext.com/case/cnty-of-butler-v-wolf-1.

[3] *Citing* Howard Markel et al., *Nonpharmaceutical Interventions Implemented by US Cities During the 1918-1919 Influenza Pandemic*, 298 JAMA 644, 647 (2007). The total duration of nonpharmaceutical interventions imposed by state and local mandate for Philadelphia and Pittsburgh were 51 and 53 days, respectively. *Id.* at 647, Table 1. This length was, generally, representative of the duration of interventions in most cities. *Id.* Seattle had the longest period of restrictions, nationwide, at 168 days from start to finish. *See also* Greg Ip, *New Thinking on Covid Lockdowns: They're Overly Blunt and Costly*, WALL ST. J., Aug. 24, 2020 ("Prior to Covid-19, lockdowns weren't part of the standard epidemic tool kit, which was primarily designed with flu in mind. During the 1918-1919 flu pandemic, some American cities closed schools, churches and theaters, banned large gatherings and funerals and restricted store hours. But none imposed stay-at-home orders or closed all nonessential businesses. No such measures were imposed during the 1957 flu pandemic, the next-deadliest one; even schools stayed open.").

[4] *Citing* Noreen Quails et al., *Community Mitigation Guidelines to Prevent Pandemic Influenza*, United States, 2017 (Sonja A. Rasmussen et al. eds., 2017).

> The fact is that the lockdowns imposed across the United States in early 2020 in response to the COVID-19 pandemic are unprecedented in the history of our Commonwealth and our Country. They have never been used in response to any other disease in our history. They were not recommendations made by the CDC. They were unheard of by the people [of] this nation until just this year. It appears as though the imposition of *lockdowns in Wuhan and other areas of China—a nation unconstrained by concern for civil liberties and constitutional norms—started a domino effect where one country, and state, after another imposed draconian and hitherto untried measures on their citizens.* (emphasis added)

Judge Stickman's intuition regarding the real history of lockdowns is in line with the opinion of the foremost infectious disease scholars. Donald Henderson, the man widely credited with eradicating smallpox, wrote in 2006, "Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted."[5] To our knowledge, no scientist ever publicly supported imposing lockdowns until Xi Jinping, General Secretary of the Chinese Communist Party (CCP), personally authorized the "unprecedented lockdown of Wuhan and other cities beginning on Jan. 23."[6]

General Secretary Xi is perhaps best known for the punishment of over one million CCP officials for "corruption,"[7] the elimination of term limits from China's constitution,[8] and, of course, the reeducation and "*quarantine*"[9] of over one million Uyghur Muslims and other minorities "*infected with extremism*"[10] throughout the regions of Xinjiang and Tibet, pursuant to the CCP's pet hybrid of public health and security policy: *fangkong*—the same policy that inspired Xi's lockdown of Hubei province.[11] General Secretary Xi later affirmed that he had issued these instructions to the CCP's Politburo Standing Committee on January 7, 2020,[12] but his instructions have never been revealed. Chinese business leader Ren Zhiqiang was sentenced to 18 years in prison[13] for an open letter in which he requested Xi's instructions be made public.[14]

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[5] Thomas V. Inglesby, Jennifer B. Nuzzo, Tara O'toole, and D. A. Henderson, *Disease Mitigation Measures in the Control of Pandemic Influenza,* Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science Vol. 4 No. 4, 2006, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.552.1109&rep=rep1&type=pdf.

[6] Amy Qin, *China's Leader, Under Fire, Says He Led Coronavirus Fight Early On*, N.Y. Times, Feb. 15, 2020, https://www.nytimes.com/2020/02/15/world/asia/xi-china-coronavirus.html.

[7] Choi Chi-yuk, *Xi Jinping's anti-graft drive has caught so many officials that Beijing's elite prison is running out of cells*, Feb. 14, 2018, South China Morning Post, https://www.scmp.com/news/china/policies-politics/article/2133251/xi-jinpings-anti-graft-drive-has-caught-so-many.

[8] Tom Phillips, *'Dictator for life': Xi Jinping's power grab condemned as step towards tyranny*, Feb. 26, 2018, The Guardian, https://www.theguardian.com/world/2018/feb/26/xi-jinping-china-presidential-limit-scrap-dictator-for-life.

[9] Austin Ramzy and Chris Buckley, *'Absolutely No Mercy': Leaked Files Expose How China Organized Mass Detentions of Muslims*, N.Y. Times, Nov. 16, 2019, https://www.nytimes.com/interactive/2019/11/16/world/asia/china-xinjiang-documents.html.

[10] Tanner Greer, *China's Plans to Win Control of the Global Order*, Tablet Magazine, May 17, 2020, https://www.tabletmag.com/sections/news/articles/china-plans-global-order.

[11] Sheena Chestnut Greitens and Julian Gewirtz, *China's Troubling Vision for the Future of Public Health*, Foreign Affairs, Jul. 10, 2020, https://www.foreignaffairs.com/articles/china/2020-07-10/chinas-troubling-vision-future-public-health.

When the lockdown of Hubei province began, the World Health Organization (WHO)'s representative in China noted that "trying to contain a city of 11 million people is new to science... The lockdown of 11 million people is unprecedented in public health history..."[15] Human rights observers also expressed concerns.[16] But those concerns didn't stop the WHO from effusively praising the CCP's "*unprecedented*" response just days after the lockdown began, and long before it had produced any results: "The measures China has taken are good not only for that country but also for the rest of the world."[17] WHO Director Tedros Adhanom added that he was personally "very impressed and encouraged by the president [Xi Jinping]'s detailed knowledge of the outbreak" and the next day praised China for "setting a new standard for outbreak response."[18]

By February 2020, the CCP had begun reporting an exponential decline in COVID-19 cases. In its February report, the WHO waxed rhapsodic about China's triumph:

> General Secretary Xi Jinping personally directed and deployed the prevention and control work ... China's *uncompromising* and *rigorous* use of non-pharmaceutical measures to contain transmission of the COVID-19 virus in multiple settings provides *vital lessons* for the global response"[19] (emphasis added).

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[12] Amy Qin, *China's Leader, Under Fire, Says He Led Coronavirus Fight Early On*, N.Y. Times, Feb. 15, 2020, https://www.nytimes.com/2020/02/15/world/asia/xi-china-coronavirus.html.

[13] Chris Buckley, *China's 'Big Cannon' Blasted Xi. Now He's Been Jailed for 18 Years*, N.Y. Times, Sep. 22, 2020, https://www.nytimes.com/2020/09/22/world/asia/china-ren-zhiqiang-tycoon.html.

[14] Josh Rudolph, *Translation: Essay by Missing Property Tycoon Ren Zhiqiang*, China Digital Times, Mar. 13, 2020, https://chinadigitaltimes.net/2020/03/translation-essay-by-missing-property-tycoon-ren-zhiqiang/.

[15] Sinéad Baker, *China extended its Wuhan coronavirus quarantine to 2 more cities, cutting off 19 million people in an unprecedented effort to stop the outbreak*, Business Insider, Jan. 23, 2020, https://www.businessinsider.com/china-wuhan-coronavirus-quarantine-extended-cities-cut-off-2020-1.

[16] *E.g.*, Frances Eve, *China's reaction to the coronavirus outbreak violates human rights*, The Guardian, Feb. 2, 2020, https://www.theguardian.com/world/2020/feb/02/chinas-reaction-to-the-coronavirus-outbreak-violates-human-rights; Michael Levenson, Scale of China's Wuhan Shutdown Is Believed to Be Without Precedent, N.Y. Times, Jan. 22, 2020, https://www.nytimes.com/2020/01/22/world/asia/coronavirus-quarantines-history.html.

[17] World Health Organization, *Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)*, Jan. 30, 2020, https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

[18] World Health Organization, *WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV)*, Jan. 30, 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-(2019-ncov).

[19] World Health Organization, *Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19)*, Feb. 16–24, 2020, https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf.

Shortly thereafter, the WHO held a press conference during which Assistant Director-General Bruce Aylward—who later disconnected a live interview when asked to acknowledge Taiwan[20]—told the press: "What China has demonstrated is, *you have to do this*. If you do it, you can save lives and prevent thousands of cases of what is a very difficult disease."[21] (emphasis added). Two days later, in an interview for China Central Television (CCTV), Aylward put it bluntly: "*Copy China's response* to COVID-19."[22] (emphasis added).

The WHO's recommendations are notable for two reasons. First, the WHO's conclusion in its February report that this "rather unique and unprecedented public health response in China reversed the escalating cases"[23] exemplifies the fallacy of *post hoc, ergo propter hoc*. While it was possible that a more "flat" curve in Wuhan could be attributed to the CCP's lockdown, it was at least equally likely that Wuhan had simply witnessed the natural course of this "novel" pathogen. It should have been obvious that the mere issuance of a policy "unprecedented in public health history" did not automatically mean it was effective—especially given the WHO's own 2019 guidance for pandemic influenza did not advise border closures, mass contact tracing, or quarantine even of "exposed individuals" under any circumstance.[24]

Furthermore, the WHO did not even consider other countries' economic circumstances, demographics, or even their *number of COVID-19 cases*—which were very few in most of the world—before instructing the entire world that "you have to do this."[25] This conclusion by the world's foremost public health body was, at best, criminally negligent.[26]

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[20] Tom Grundy, *Video: Top WHO doctor Bruce Aylward ends video call after journalist asks about Taiwan's status*, Hong Kong Free Press, Mar. 29, 2020, https://hongkongfp.com/2020/03/29/video-top-doctor-bruce-aylward-pretends-not-hear-journalists-taiwan-questions-ends-video-call/. In April, Canada's parliament summoned Aylward for questioning, but the WHO has forbidden him from testifying. Steven Chase, *MPs vote to summon key WHO adviser after global body refuses to let him testify*, The Globe and Mail, Apr. 30, 2020, https://www.theglobeandmail.com/canada/article-mps-vote-to-summon-key-who-adviser-after-global-body-refuses-to-let/; True North, *WHO forbids Canadian official from testifying before health committee*, Aug. 19, 2020, https://tnc.news/2020/08/19/who-forbids-canadian-official-from-testifying-before-health-committee/.

[21] World Health Organization, *Subject: Press Conference of WHO-China Joint Mission on COVID-19*, Feb. 24, 2020, https://www.who.int/docs/default-source/coronaviruse/transcripts/joint-mission-press-conference-script-english-final.pdf?sfvrsn=51c90b9e_2.

[22] Daniel Harries, *'Copy China's response to COVID-19,' WHO expert urges rest of the world*, CGTN, Feb. 26, 2020, https://newseu.cgtn.com/news/2020-02-26/-Copy-China-s-response-to-COVID-19-WHO-expert-urges--OnNfwORI3u/index.html.

[23] World Health Organization, *Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19)*, Feb. 16–24, 2020, https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf.

[24] World Health Organization, *Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza*, 2019, https://apps.who.int/iris/bitstream/handle/10665/329438/9789241516839-eng.pdf?ua=1.

Lockdowns are a Xi Jinping policy, and the significance of that fact cannot be overstated. The idea of locking down an entire state or country and forcibly shutting down its businesses and public places was never entertained, never discussed, and never implemented in any pandemic literature until it was done by General Secretary Xi in January 2020. Lockdowns were never tried before 2020 and never tested before 2020, even on a theoretical basis.[27] The idea of "lockdown" was brought into human history on the order of General Secretary Xi; it otherwise never would have entered the collective human imagination. Anytime anyone endorses a lockdown for any length of time, even a few minutes, they are endorsing a Xi Jinping policy. The remainder of this letter concerns *how* lockdowns were laundered into the world's go-to pandemic policy.

2. The Most Influential Institution for Covid-19 Models, Self-Described as "China's Best Academic Partner in the West," Has Been by Far the Most Alarmist and Inaccurate Covid-19 Modeler

In February 2020, a team from Imperial College London led by physicist Neil Ferguson ran a computer model that played an outsized role in justifying lockdowns in most countries. Imperial College forecast a number of potential outcomes, including that, by October 2020, more than 500,000 people in Great Britain and 2.2 million people in the U.S. would die as a result of COVID-19, and recommended months of strict social distancing measures to prevent this outcome.[28] The model also predicted the United States could incur up to one million deaths even with "enhanced social distancing" guidelines, including "shielding the elderly."[29] In reality, by the end of October, according to the CDC and the United Kingdom National Health Service (NHS), approximately 230,000 deaths[30] in the United States and 37,000 deaths[31] in the United

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[25] World Health Organization, *Subject: Press Conference of WHO-China Joint Mission on COVID-19*, Feb. 24, 2020, https://www.who.int/docs/default-source/coronaviruse/transcripts/joint-mission-press-conference-script-english-final.pdf?sfvrsn=51c90b9e_2.

[26] Stacey Rudin, *What's Behind The WHO's Lockdown Mixed-Messaging*, American Institute for Economic Research, Oct. 14, 2020, https://www.aier.org/article/whats-behind-the-whos-lockdown-mixed-messaging/.

[27] Noreen Quails *et al.*, *Community Mitigation Guidelines to Prevent Pandemic Influenza*, United States, 2017 (Sonja A. Rasmussen et al. eds., 2017), https://www.cdc.gov/mmwr/volumes/66/rr/rr6601a1.htm.

[28] Neil M Ferguson *et al.*, *Report 9: Impact of non-pharmaceutical interventions (NPIs) to reduce COVID-19 mortality and healthcare demand*, Imperial College COVID-19 Response Team, Mar. 16, 2020, https://www.imperial.ac.uk/media/imperial-college/medicine/sph/ide/gida-fellowships/Imperial-College-COVID19-NPI-modelling-16-03-2020.pdf.

[29] Neil M Ferguson *et al.*, *Report 12: The Global Impact of COVID-19 and Strategies for Mitigation and Suppression*, Imperial College COVID-19 Response Team, Mar. 16, 2020, https://www.imperial.ac.uk/media/imperial-college/medicine/mrc-gida/2020-03-26-COVID19-Report-12.pdf.

[30] Centers for Disease Control and Prevention, *Provisional Death Counts for Coronavirus Disease 2019 (COVID-19)*, https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.

Kingdom had been attributed to COVID-19 (though deaths from all other leading causes—including heart disease, cancer, and influenza—mysteriously declined,[32] indicating that even these low counts from the CDC and NHS are vastly overstated).

A study by researchers at UCLA and the Institute for Health Metrics and Evaluation (IHME) compared the accuracy of various institutions' models predicting COVID-19 mortality.[33] Across all time periods, the models produced by Imperial College were measured to have far higher rates of error than the others—*always* erring on the side of being too high:

> The 12-week median absolute percent errors (MAPE), reflecting models produced in July and August, ranged from 22.4% for the SIK-J Alpha model, to 79.9% for the Imperial model… The Delphi and LANL models from July underestimated mortality, with median percent errors of -5.6% and -8.3% at 6 weeks respectively, while Imperial tended to overestimate (+47.7%), and the remaining models were relatively unbiased… The Imperial model had *larger errors, about 5-fold higher* than other models by six weeks. This appears to be largely driven by the aforementioned *tendency to overestimate mortality*. At twelve weeks, MAPE values were lowest for the IHME-MS-SEIR (23.7%) model, while the Imperial model had the most elevated MAPE (98.8%)… In the most current models, the 6-week MAPE across models was 7.2%.

Imperial's inaccuracy continued unabated. In October 2020, Imperial College's model predicted the U.K. would experience 2,000 deaths per day by mid-December.[34] In fact, deaths per day in the U.K. never reached 400, per NHS.[35]

Five years earlier, on October 21, 2015, General Secretary Xi personally visited Imperial College London for the announcement of "a series of new UK-China education and research collaborations" including "nanotechnology, bioengineering… and public health."[36] This was the only trip Xi ever made to the U.K. as General Secretary; the trip lasted just four days and

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[31] National Health Service, *COVID-19 Daily Deaths*, https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-daily-deaths/.

[32] Yanni Gu, *A closer look at U.S. deaths due to COVID-19*, Johns Hopkins News-Letter, Nov. 22, 2020, https://web.archive.org/web/20201122214034/https://www.jhunewsletter.com/article/2020/11/a-closer-look-at-u-s-deaths-due-to-covid-19.

[33] Joseph Friedman *et al.*, *Predictive performance of international COVID-19 mortality forecasting models*, Nov. 19, 2020, https://doi.org/10.1101/2020.07.13.20151233.

[34] Scientific Advisory Group for Emergencies, *SPI-M-O: Long term winter scenarios preparatory working analysis*, Oct. 31, 2020, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/938967/201031_SPI-M_preparatory_analysis_long_term_scenarios.pdf.

[35] National Health Service, *COVID-19 Daily Deaths*, https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-daily-deaths/.

[36] Andrew Scheuber, *Chinese President sees UK-China academic partnerships at Imperial*, Imperial College London, Oct. 21, 2015, https://www.imperial.ac.uk/news/168497/chinese-president-sees-uk-china-academic-partnerships/.

involved just one university: Imperial College London.[37] In a speech welcoming General Secretary Xi and his wife, Peng Liyuan, a goodwill ambassador to the WHO, Imperial College President Alice Gast addressed the Chancellor of the Exchequer:

> Chancellor, you have said that you aim to make the U.K. 'China's best partner in the west.' Imperial College London strives to be just that, *China's best academic partner in the west…* As China's top research partner in the U.K., Imperial's academics and students benefit from collaboration on a daily basis.[38] (emphasis added)

In 2019, Gast became part of the notably pro-China[39] World Economic Forum's AI Council along with Chinese AI Expert and venture capitalist Kai-Fu Lee, and to this day, Imperial College continues to advertise itself as "UK's number one university collaborator with Chinese research institutions."[40]

In March 2020, Imperial College produced a report titled "Evidence of initial success for China exiting COVID-19 social distancing policy after achieving containment," concluding:

> For the first time since the outbreak began there have been no new confirmed cases caused by local transmission in China reported for five consecutive days up to 23 March 2020. This is an indication that the social distancing measures enacted in China have led to control of COVID-19 in China… after very intense social distancing which resulted in containment, China has successfully exited their stringent social distancing policy to some degree.[41]

Imperial College had no way of knowing if this was, in fact, true—failing to discover cases does not mean they do not exist, particularly with a virus that is fatal to hardly anyone except the most vulnerable, and a regime with a long history of fraud—and its conclusion directly contradicted that of the U.S. intelligence community around the same time that China had intentionally misrepresented its coronavirus numbers.[42] In a December interview, Neil Ferguson recalled how China had inspired his lockdown recommendations to the U.K.'s Scientific Advisory Group for Emergencies (SAGE):

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[37] Wikipedia, *2015 Xi Jinping visit to the United Kingdom*, https://en.wikipedia.org/wiki/2015_Xi_Jinping_visit_to_the_United_Kingdom.

[38] Andrew Scheuber, *Chinese President sees UK-China academic partnerships at Imperial*, Imperial College London, Oct. 21, 2015, https://www.imperial.ac.uk/news/168497/chinese-president-sees-uk-china-academic-partnerships/.

[39] Peter S. Goodman, *In Era of Trump, China's President Champions Economic Globalization*, N.Y. Times, Jan. 17, 2017, https://www.nytimes.com/2017/01/17/business/dealbook/world-economic-forum-davos-china-xi-globalization.html; *see also* Aya Velázquez, *China Und Der Great Reset*, Demokratischer Widerstand, Nov. 27, 2020, https://demokratischerwiderstand.de/artikel/158/china-und-der-great-resetWeitere.

[40] David Lee, *World Economic Forum Establishes "A.I. Council" Co-chaired by Chinese AI Expert Kai-Fu Lee*, Pandaily, Jan. 24, 2019, https://pandaily.com/world-economic-forum-establishes-artificial-intelligence-council/; Imperial College London, *China and Imperial*, https://web.archive.org/web/20201231155935/https://www.imperial.ac.uk/about/introducing-imperial/global-imperial/east-asia/china/.

[41] Neil M Ferguson and Steven Riley *et al.*, *Report 11 - Evidence of initial success for China exiting COVID-19 social distancing policy after achieving containment*, Imperial College COVID-19 Response Team, Mar. 24, 2020, https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-11-china-exiting-social-distancing/.

> I think people's sense of what is possible in terms of control changed quite dramatically between January and March… It's a communist one party state, we said. We couldn't get away with it in Europe, we thought… And then Italy did it. And we realised we could… If China had not done it, the year would have been very different.[43]

In a time of panic, it's natural for the public to focus on the worst possible outcomes. Thus, a prestigious institution producing particularly alarmist models can have an outsized impact on political discourse. In this case, the institution in question not only consistently and egregiously erred in just one direction—the "tendency to overestimate mortality"—but also had a special relationship with China as its "best academic partner in the west."

3. Deadly Recommendations for Early Mechanical Ventilation Came from China

In early March 2020, the WHO released COVID-19 provider guidance documents to healthcare workers.[44] The guidance recommended escalating quickly to mechanical ventilation as an early intervention for treating COVID-19 patients, a departure from past experience during respiratory-virus epidemics.[45] In doing so, they cited the guidance being presented by Chinese journal articles, which published papers in January and February claiming that "*Chinese expert consensus*" called for "invasive mechanical ventilation" as the "first choice" for people with moderate to severe respiratory distress,[46] in part to protect medical staff. As the Wall Street Journal later reported:

> Last spring, doctors put patients on ventilators partly to limit contagion at a time when it was less clear how the virus spread, when protective masks and gowns were in short supply. Doctors could have employed other kinds of breathing support devices that don't

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[42] Sonam Sheth and Isaac Scher, *The US intelligence community has reportedly concluded that China intentionally misrepresented its coronavirus numbers*, Business Insider, Apr. 1, 2020, https://www.businessinsider.com/us-intelligence-found-china-misrepresented-coronavirus-stats-report-2020-4.

[43] Tom Whipple, *Professor Neil Ferguson: People don't agree with lockdown and try to undermine the scientists*, The Times of London, Dec. 25, 2020, https://www.thetimes.co.uk/article/people-don-t-agree-with-lockdown-and-try-to-undermine-the-scientists-gnms7mp98.

[44] World Health Organization, *Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected*, Mar. 13, 2020, https://www.who.int/docs/default-source/coronaviruse/clinical-management-of-novel-cov.pdf.

[45] Philippe Rola *et al.*, *Rethinking the early intubation paradigm of COVID-19: time to change gears?*, Clin Exp Emerg Med Vol. 7(2), Jun. 10, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7348679/.

[46] Fujun Peng *et al.*, *Management and Treatment of COVID-19: The Chinese Experience*, Can J Cardiol Vol. 36(6), Apt. 17, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7162773/.

> require risky sedation, but early reports suggested patients using them could spray dangerous amounts of virus into the air, said Theodore Iwashyna, a critical-care physician at University of Michigan and Department of Veterans Affairs hospitals in Ann Arbor, Mich.
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> At the time, he said, doctors and nurses feared the virus would spread through hospitals. "*We were intubating sick patients very early. Not for the patients' benefit, but in order to control the epidemic* and to save other patients," Dr. Iwashyna said "That felt awful."[47] (emphasis added)

In New York and other cities, early and often ventilator use became a common theme, and it had devastating consequences for patients.[48] On March 31, 2020, Dr. Cameron Kyle-Sidell, who had been caring for ICU patients at one of the hardest-hit hospitals in New York City, acted as an early whistleblower, sounding the alarm about the ventilator issue in a widely-shared video:

> We are operating under a medical paradigm that is untrue... I fear that this misguided treatment will lead to a tremendous amount of harm to a great number of people in a very short time... I don't know the final answer to this disease, but I'm quite sure that a ventilator is not it... This method being widely adopted at this very moment at every hospital in the country ... is actually doing more harm than good.[49]

An April Reuters interview with dozens of medical specialists made it clear that mechanical ventilator overuse had become a global issue: "Many highlighted the risks from using the most invasive types of them - mechanical ventilators - too early or too frequently, or from non-specialists using them without proper training in overwhelmed hospitals."[50]

By May 2020, it was common knowledge in the medical community that early ventilator use was hurting, not helping, COVID-19 patients, and that less invasive measures were in fact very effective in assisting recoveries.[51] A New York City study found a *97.2% mortality rate* among those over age 65 who received mechanical ventilation.[52] The "early action" ventilator guidance that the WHO distributed to the world killed thousands of innocent patients; the WHO obtained that guidance from China.

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[47] Melanie Evans, *Hospitals Retreat From Early Covid Treatment and Return to Basics*, Wall Street Journal, Dec. 20, 2020, https://www.wsj.com/articles/hospitals-retreat-from-early-covid-treatment-and-return-to-basics-11608491436.

[48] Jordan Schachtel, *'First Choice': How China and the WHO created mass ventilator hysteria*, Sep. 30, 2020, https://jordanschachtel.substack.com/p/first-choice-how-china-and-the-who.

[49] Cameron Kyle-Sidell, *From NYC ICU: Does Covid-19 Really Cause ARDS??!!*, YouTube, Mar. 31, 2020, https://www.youtube.com/watch?v=k9GYTc53r2o&feature=youtu.be.

[50] Silvia Aloisi *et al.*, *Special Report: As virus advances, doctors rethink rush to ventilate*, Reuters, Apr. 23, 2020, https://www.reuters.com/article/us-health-coronavirus-ventilators-specia/as-virus-advances-doctors-rethink-rush-to-ventilate-idUSKCN2251PE.

[51] Sharon Begley, *With ventilators running out, doctors say the machines are overused for Covid-19*, Stat, Apr. 8, 2020, https://www.statnews.com/2020/04/08/doctors-say-ventilators-overused-for-covid-19/.

4. The World's Predominant, Wildly-Inaccurate PCR Testing Protocols Are Based on Incomplete, Theoretical Genome Sequences Supplied by China

Virologists Victor Corman and Christian Drosten led the exceptionally-rapid creation of the first COVID-19 PCR test (the "Corman-Drosten Protocol");[53] it is now the most commonly-used testing protocol in the world for detecting the SARS-CoV-2 virus which may, in certain cases, lead to the disease COVID-19. (As discussed *infra*, the Court of Appeal of Lisbon concluded that this PCR test was producing as many as 97% false positives). Corman and Drosten were provided with the *in silico* (theoretical) genome sequences used to create their PCR protocol by Chinese scientists including Yong-Zhen Zhang and Shi Zhengli, Director at the Wuhan Institute of Virology.[54] (These genome sequences were then posted to the open-source depository Virological.org on January 10, 2020). The Corman-Drosten Protocol was submitted to the WHO on January 13,[55] eight days *prior* to the date it was submitted to the medical journal Eurosurveillance for "peer review."[56]

The WHO released the Corman-Drosten Protocol on January 21, the same day it was submitted to Eurosurveillance.[57] Drosten sits on the board of Eurosurveillance, a conflict of interest.[58] The Corman-Drosten Protocol was accepted[59] by Eurosurveillance the *very next* day, January 22 (the same day the WHO confirmed human-to-human transmission),[60] an extraordinarily quick turnaround; peer review for scientific journals is an intensive process requiring identification of, and action by, external reviewers, which typically takes weeks to months. Of all 1,595 publications at Eurosurveillance since 2015, not one other research paper was reviewed and accepted in fewer than 20 days.[61] Eurosurveillance's peer review process also requires an author declaration that no conflicts of interest exist, which was, in this case, a false statement.[62] This extraordinarily quick turnaround made it impossible for any other PCR protocol to be published before the Corman-Drosten Protocol, which was published on PubMed on January 23,[63] giving it a valuable "first-mover" advantage ensuring that it became the predominant PCR protocol in the world.

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[52] Safiya Richardson, MD, MPH, *et al.*, *Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area*, JAMA 2020 323(20), Apr. 22, 2020, https://jamanetwork.com/journals/jama/fullarticle/2765184.

[53] Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, World Health Organization, Jan. 17, 2020, https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf.

[54] Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, Eurosurveillance European Communicable Disease Bulletin Vol. 25(3), Jan. 23, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6988269/.

[55] Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, World Health Organization, Jan. 13, 2020, https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf.

[56] Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, Eurosurveillance European Communicable Disease Bulletin Vol. 25(3), Jan. 23, 2020, https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045.

[57] Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, World Health Organization, Jan. 17, 2020, https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf.

[58] Eurosurveillane, *Editorial Board*, https://web.archive.org/web/20201224033649/https://www.eurosurveillance.org/board.

[59] Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, Eurosurveillance European Communicable Disease Bulletin Vol. 25(3), Jan. 23, 2020, https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045.

[60] World Health Organization, *Archived: WHO Timeline - COVID-19*, Apr. 27, 2020, https://www.who.int/news/item/27-04-2020-who-timeline---covid-19.

The molecular biologist Pieter Borger and his team submitted a retraction request for the Corman-Drosten PCR protocol.[64] According to Borger's report, the Corman-Drosten PCR test workflow contains multiple, fatal errors. The most glaring issue is the fact that, at the time the protocol was submitted, there was no good reason to believe widespread PCR testing would even be necessary:

> The authors introduce the background for their scientific work as: "The ongoing outbreak of the recently emerged novel coronavirus (2019-nCoV) poses a challenge for public health laboratories as virus isolates are unavailable while there is growing evidence that the outbreak is more widespread than initially thought, and international spread through travelers does already occur.
>
> According to BBC News[65] and Google Statistics[66] there were 6 deaths world-wide on January 21st 2020 – the day when the manuscript was submitted. Why did the authors *assume a challenge for public health laboratories while there was no substantial evidence at that time to indicate that the outbreak was more widespread* than initially thought? (emphasis added)

Borger's report goes on to specify ten major flaws with the Corman-Drosten protocol, the biggest issue being the fact that the entire test is based on *in silico* (theoretical) sequences supplied by China:

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[61] @waukema, Twitter, Nov. 30, 2020, https://twitter.com/waukema/status/1333612453561831428.

[62] Eurosurveillane, *Evaluation and review process*, https://www.eurosurveillance.org/evaluation.

[63] Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, Eurosurveillance European Communicable Disease Bulletin Vol. 25(3), Jan. 23, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6988269/.

[64] Pieter Borger *et al.*, *External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results*, Nov. 27, 2020, https://cormandrostenreview.com/report/.

[65] *Citing* New China virus: Warning against cover-up as number of cases jumps, BBC, Jan. 21, 2020, https://www.bbc.com/news/world-asia-china-51185836.

[66] *Citing* Google Analytics – COVID19-deaths worldwide, https://archive.is/PpqEE.

> The first and major issue is that the novel Coronavirus SARS-CoV-2 (in the publication named 2019-nCoV and in February 2020 named SARS-CoV-2 by an international consortium of virus experts) is based on *in silico* sequences, supplied by a laboratory in China,[67] because at the time neither control material of infectious ("live") or inactivated SARS-CoV-2 nor isolated genomic RNA of the virus was available to the authors. To date no validation has been performed by the authorship based on isolated SARS-CoV-2 viruses or full length RNA thereof.

In addition, the primers and probes in Drosten's protocol are incomplete and non-specific; the primer concentrations are four to five times too high; the GC content (connection strength) is far too low; the annealing temperature difference in primer pairs is up to five times too high; the PCR products have not been validated at the molecular level, rendering the test useless as a specific diagnostic tool to identify SARS-CoV-2; and—given the protocol was accepted for publication just one day after it was submitted to Eurosurveillance—it was obviously never subjected to any meaningful peer review.

Corman and Drosten's PCR protocol thus has every indication of being fraudulent.

In June, a peer-reviewed study was published comparing the accuracy of the COVID-19 PCR test protocols on the short list recommended by the WHO. The PCR protocol developed by the CDC (the N2 US CDC protocol)[68]—likewise based on *in silico* genome sequences supplied by China—fared little better than the Corman-Drosten protocol:

> The E Charité [Corman-Drosten] and N2 US CDC assays were positive for all specimens, including negative samples and negative controls (water).[69]

Together, these two PCR protocols account for the majority of COVID-19 PCR tests conducted in the Nations.[70] Both rely on *in silico* sequences from China, and both produce wildly inaccurate results, testing positive for all specimens including negative samples and plain water.

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[67] *Citing* Victor Corman and Christian Drosten *et al.*, *Diagnostic detection of 2019-nCoV by real-time RT-PCR*, Eurosurveillance European Communicable Disease Bulletin Vol. 25(3), Jan. 23, 2020, https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045.

[68] Centers for Disease Control and Prevention Division of Viral Diseases, *CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel*, Feb. 4, 2020, http://web.archive.org/web/20200227050956/https://www.fda.gov/media/134922/download.

[69] Sibyle Etievant *et al.*, *Performance Assessment of SARS-CoV-2 PCR Assays Developed by WHO Referral Laboratories*. J Clin Med Vol. 9(6), Jun. 16, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7355678/.

[70] World Health Organization, *Summary table of available protocols in this document*, http://web.archive.org/web/20200909015002/https://www.who.int/docs/default-source/coronaviruse/whoinhouseassays.pdf.

5. Predominant, Excessive PCR Testing Protocols Came from China

In accordance with recommendations by the WHO and other public health authorities, countless laboratories have engaged in mass PCR testing for the SARS-CoV-2 virus.[71] Fundamental to PCR testing is the concept of "cycle thresholds." The PCR test amplifies genetic matter from a virus in cycles; the fewer cycles required, the greater the amount of virus, or viral load, in the sample. The greater the viral load, the more likely the patient is to be contagious. Thus, the higher the PCR cycle threshold, the lower the amount of viral load needed to trigger a positive PCR test.

If the PCR cycle threshold indicating a "positive" is set too high, a positive result may not even indicate any meaningful amount of live viral particles. As Dr. Anthony Fauci mentioned in a July 2020 interview, a cycle threshold of 35 or more should not be considered a positive result:

> What is now sort of evolving into a bit of a standard ... if you get a cycle threshold of 35 or more ... the chances of it being replication-confident are minuscule... So, I think if somebody does come in with *37, 38, even 36, you got to say, you know, it's just dead nucleotides, period.*[72] (emphasis added)

The WHO published its currently-outstanding guidance on laboratory testing for COVID-19 on March 19, 2020.[73] The WHO's guidance contained only three studies discussing PCR cycle thresholds. All three studies[74] are from China and use cycle thresholds from 37 to 40: "A cycle threshold value (Ct-value) less than 37 was defined as a positive test, and a Ct-value of 40 or more was defined as a negative test."[75]

As described by the New York Times, most laboratories and manufacturers in the United States now set their cutoff for a positive PCR test from 37 to 40 cycle thresholds: "Most tests set the limit at 40, a few at 37. This means that you are positive for the coronavirus if the test process required up to 40 cycles, or 37, to detect the virus."[76] At 37 cycles, any viral RNA or DNA will have been amplified over 68 billion times, and at 40 cycles it will have been amplified over 500 billion times.

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[71] World Health Organization, *Laboratory testing for coronavirus disease (COVID-19) in suspected human cases*, Mar. 19, 2020, https://apps.who.int/iris/bitstream/handle/10665/331501/WHO-COVID-19-laboratory-2020.5-eng.pdf?sequence=1&isAllowed=y.

[72] Daniel Payne, *In little noticed July interview, Fauci warned that widely used COVID tests may pick up 'dead' virus*, Just the News, Dec. 10, 2020, https://justthenews.com/politics-policy/coronavirus/newly-surfaced-video-july-fauci-tests-dead-virus.

[73] World Health Organization, *Laboratory testing for coronavirus disease (COVID-19) in suspected human cases*, Mar. 19, 2020, https://apps.who.int/iris/bitstream/handle/10665/331501/WHO-COVID-19-laboratory-2020.5-eng.pdf?sequence=1&isAllowed=y.

[74] Qun Li *et al.*, *Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia*, N Engl J Med Vol. 382(13), Jan. 29, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7121484/; *Clinical Characteristics of Coronavirus Disease 2019 in China*, N Engl J Med Vol. 382, Feb. 28, 2020, https://www.nejm.org/doi/10.1056/NEJMoa2002032; Wei Zhang *et al.*, *Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes*, Emerg Microbes Infect Vol. 9(1), Feb. 17, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7048229/.

[75] Qun Li *et al.*, *Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia*, N Engl J Med Vol. 382(13), Jan. 29, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7121484/.

Doctors interviewed by the New York Times agreed with Dr. Fauci that anything above 35 cycle thresholds is too sensitive. "A more reasonable cutoff would be 30 to 35," said Juliet Morrison, virologist at UC Riverside. Dr. Michael Mina, epidemiologist at the Harvard T.H. Chan School of Public Health, said he would set the figure at 30, or even less. Using current testing standards with 37 to 40 cycle thresholds:

> In three sets of testing data that include cycle thresholds, compiled by officials in Massachusetts, New York and Nevada, up to 90 percent of people testing positive carried barely any virus, a review by The Times found... In Massachusetts, from *85 to 90 percent* of people who tested positive in July with a cycle threshold of 40 would have been deemed negative if the threshold were 30 cycles, Dr. Mina said. 'I would say that none of those people should be contact-traced, not one,' he said.[77] (emphasis added).

In a recent ruling, the Court of Appeal of Lisbon concluded: "In view of current scientific evidence, this test shows itself to be unable to determine beyond reasonable doubt that such positivity corresponds, in fact, to the infection of a person by the SARS-CoV-2 virus."[78] The two most important reasons for this, said the judges, are that, "the test's reliability depends on the number of cycles used'' and that "the test's reliability depends on the viral load present."[79]

The court cited a study conducted by "some of the leading European and world specialists," showing that if someone tested positive for COVID-19 at a cycle threshold of 35 or higher, the chance of that person actually being infected is less than 3%, and that "the probability of... receiving a false positive is 97% or higher."[80]

To summarize, based on guidance issued by the WHO citing three studies from China, laboratories and manufacturers across the United States and many other countries are using a PCR cycle threshold of 37 to 40 for COVID-19 PCR tests that were created using *in silico* genome sequences supplied by a laboratory in China, pursuant to which positive COVID-19 case counts have been inflated as much as ten- to thirty-fold.[81]

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[76] Apoorva Mandavilli, *Your Coronavirus Test Is Positive. Maybe It Shouldn't Be.*, N.Y. Times, Aug. 29, 2020, https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html.

[77] *Id.*

[78] Natasha Donn, *Judges in Portugal highlight "more than debatable" reliability of Covid tests*, Portugal Resident, Nov. 20, 2020, https://www.portugalresident.com/judges-in-portugal-highlight-more-than-debatable-reliability-of-covid-tests/.

[79] Court of Appeal of Lisbon, judgment of 11-11-2020 in Proceedings No. 1783/20.7T8PDL.L1-3, https://translate.google.com/translate?hl=&sl=pt&tl=en&u=http%3A%2F%2Fwww.dgsi.pt%2Fjtrl.nsf%2F33182fc7323160398025 65fa00497eec%2F79d6ba338dcbe5e28025861f003e7b30.

[80] *Id.*

6. Studies Showing Significant Asymptomatic Transmission, the Only Scientific Basis for Lockdowns of Healthy Individuals, Came from China

Underpinning the policy of "lockdown" is the scientific concept of "asymptomatic spread." According to the WHO, "Early data from China suggested that people without symptoms could infect others."[82] This idea of asymptomatic spread was reflected in the WHO's February report.[83] According to this concept, healthy individuals, or "silent spreaders" might be responsible for a significant number of SARS-CoV-2 transmissions.[84] The idea of setting out to stop asymptomatic spread was a significant departure from prevailing public health guidance and experience during prior respiratory-virus pandemics.[85]

The concept of significant asymptomatic spread was believed to be a novel and unique feature of SARS-CoV-2 based on several studies performed in China.[86] Multiple studies from other countries could not find any transmission of SARS-CoV-2 from asymptomatic individuals.[87]

A paper from McGill University concluded that "transmission in the asymptomatic period was documented in numerous studies," but every one of those studies was conducted in China; where studies outside of China have tried to replicate these findings, they have failed.[88] An Italian study concluded that two asymptomatic individuals who tested positive had been infected by two other asymptomatic individuals, but this was based on 2,800 PCR tests; given the false-positive rate discussed above, the conclusion is dubious.[89] An influential study from Brunei Darussalam found significant asymptomatic spread,[90] but its findings are considerably weakened by a poor case definition; its two findings of asymptomatic spread were that of a young girl with no symptoms who allegedly spread SARS-CoV-2 to her teacher who had "a mild cough on one day," and a father who remained asymptomatic but whose wife briefly had a runny nose and whose baby also had a mild cough one day.[91]

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[81] *Id.*

[82] World Health Organization, *Transmission of SARS-CoV-2: implications for infection prevention precautions*, Jul. 9, 2020, https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions.

[83] World Health Organization, *Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19)*, Feb. 16–24, 2020, https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf.

[84] Pien Huang, *What We Know About The Silent Spreaders Of COVID-19*, NPR, Apr. 13, 2020, https://www.npr.org/sections/goatsandsoda/2020/04/13/831883560/can-a-coronavirus-patient-who-isnt-showing-symptoms-infect-others.

[85] Noreen Quails *et al.*, *Community Mitigation Guidelines to Prevent Pandemic Influenza*, United States, 2017 (Sonja A. Rasmussen et al. eds., 2017), https://www.cdc.gov/mmwr/volumes/66/rr/rr6601a1.htm.

[86] World Health Organization, *Transmission of SARS-CoV-2: implications for infection prevention precautions*, Jul. 9, 2020, https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions; Lei Luo *et al.*, *Modes of contact and risk of transmission in COVID-19 among close contacts*, Mar. 26, 2020, https://doi.org/10.1101/2020.03.24.20042606; Lei Huang *et al.*, *Rapid asymptomatic transmission of COVID-19 during the incubation period demonstrating strong infectivity in a cluster of youngsters aged 16-23 years outside Wuhan and characteristics of young patients with COVID-19: A prospective contact-tracing study*, J Infect Vol. 80(6), Apr. 10, 2020, https://doi.org/10.1016/j.jinf.2020.03.006; Quan-Xin Long *et al.*, *Clinical and immunological assessment of asymptomatic SARS-CoV-2 infections*, Nat Med Vol. 26, Jun. 18, 2020, https://doi.org/10.1038/s41591-020-0965-6.

[87] Hao-Yuan Cheng, MD, MSc *et al.*, *Contact Tracing Assessment of COVID-19 Transmission Dynamics in Taiwan and Risk at Different Exposure Periods Before and After Symptom Onset*, JAMA Intern Med Vol. 180(9), May 1, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7195694/; Shin Young Park *et al.*, *Coronavirus Disease Outbreak in Call Center, South Korea*, Emerg Infect Dis Vol. 26(8), Apr. 23, 2020, https://wwwnc.cdc.gov/eid/article/26/8/20-1274_article.

A German study co-authored by Christian Drosten claimed to have found "Transmission of 2019-nCoV Infection from an Asymptomatic Contact in Germany,"[92] but the researchers didn't actually speak to the woman before they published the paper, and officials later confirmed that she did, in fact, have symptoms while in Germany.[93]

Absent this concept of significant asymptomatic spread, there is no scientific case for locking down healthy persons. This concept of significant asymptomatic transmission of SARS-CoV-2, and the studies backing it, came from China.

7. The CCP Engaged in an Early, Broad, Systematic, and Global Propaganda Campaign to Promote Its Lockdown Response

After concluding the CCP's lockdowns had "reversed the escalating cases" in China, the WHO was not alone in imploring the world to "Copy China's response to COVID-19." Beginning the same day the CCP locked down Hubei province, "leaked" videos from Wuhan began flooding international social media sites including Facebook, Twitter, and YouTube—all of which are blocked in China—purporting to show the horrors of Wuhan's epidemic and the seriousness of its lockdown, in scenes likened to *Zombieland* and *The Walking Dead*.[94] Official Chinese accounts widely shared an image of a hospital wing supposedly constructed in one day, but which actually showed an apartment 600 miles away.[95]

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[88] Mercedes Yanes-Lane *et al.*, *Proportion of asymptomatic infection among COVID-19 positive persons and their transmission potential: A systematic review and meta-analysis*, PLoS One, Nov. 3, 2020, https://doi.org/10.1371/journal.pone.0241536.

[89] Enrico Lavezzo *et al.*, *Suppression of a SARS-CoV-2 outbreak in the Italian municipality of Vo'*, Nature Vol. 584, Jun. 30, 2020, https://www.nature.com/articles/s41586-020-2488-1.

[90] Liling Chaw *et al.*, *Analysis of SARS-CoV-2 Transmission in Different Settings, Brunei*, Emerg Infect Dis Vol. 26(11), Oct. 9, 2020, https://wwwnc.cdc.gov/eid/article/26/11/20-2263_article.

[91] Justin Wong *et al.*, *Asymptomatic transmission of SARS-CoV-2 and implications for mass gatherings*, Influenza Other Respir Viruses Vol. 14(5), May 30, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7300701/.

[92] Christian Drosten, M.D. *et al.*, *Transmission of 2019-nCoV Infection from an Asymptomatic Contact in Germany*, N Engl J Med Vol. 382, Jan. 30, 2020, https://www.nejm.org/doi/full/10.1056/NEJMc2001468.

[93] Kai Kupferschmidt, *Study claiming new coronavirus can be transmitted by people without symptoms was flawed*, Science, Feb. 3, 2020, https://www.sciencemag.org/news/2020/02/paper-non-symptomatic-patient-transmitting-coronavirus-wrong.

[94] Brendan McFadden, *Coronavirus: Infected people seen 'dead in streets' in Chinese city dubbed 'zombieland'*, Daily Mirror, Jan. 24, 2020, https://www.mirror.co.uk/news/world-news/infected-people-seen-dead-streets-

Then, beginning in March 2020, the entire world was bombarded with propaganda extolling the virtues of China's heavy-handed approach.[96] Chinese state media bought numerous Facebook ads[97] advertising China's pandemic response (all of which ran without Facebook's required political disclaimer), and began erroneously describing "herd immunity"—the inevitable endpoint of every epidemic either by naturally-acquired immunity[98] or vaccination—as a "strategy" violating "human rights."[99] Sweden, whose leaders were unique in foregoing lockdowns, became a primary target of the CCP's propaganda campaign.[100] In the words of China's state-run Global Times:

> Chinese analysts and netizens doubt herd immunity and called it a violation of human rights, citing high mortality in the country compared to other Northern European countries. "So-called human rights, democracy, freedom are heading in the wrong direction in Sweden, and countries that are extremely irresponsible do not deserve to be China's friend ..."[101]

That was, of course, before the WHO adopted the bold, contradictory strategy of attempting to rewrite the historical definition of herd immunity wholesale. As recently as June 2020, the WHO's definition of herd immunity had properly included "immunity developed through

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21347952; Simon Osborne, *'Like Walking Dead' Coronavirus hell as corpses litter hospitals while people drop dead*, Daily Express, Jan. 24, 2020, https://www.express.co.uk/news/world/1232931/coronavirus-outbreak-wuhan-hospital-footage-corpses-corridors-china; Li Yuan, *A Generation Grows Up in China Without Google, Facebook or Twitter*, N.Y. Times, Aug. 6, 2018, https://www.nytimes.com/2018/08/06/technology/china-generation-blocked-internet.html.

[95] Jane Lytvynenko, *Chinese State Media Spread A False Image Of A Hospital For Coronavirus Patients In Wuhan*, BuzzFeed News, Jan. 27, 2020, https://www.buzzfeednews.com/article/janelytvynenko/china-state-media-false-coronavirus-hospital-image.

[96] Raymond Zhong *et al.*, *Behind China's Twitter Campaign, a Murky Supporting Chorus*, N.Y. Times, Jun. 8, 2020, https://www.nytimes.com/2020/06/08/technology/china-twitter-disinformation.html.

[97] Laurence Dodds, *China floods Facebook with undeclared coronavirus propaganda ads blaming Trump*, Daily Telegraph, Apr. 5, 2020, https://www.telegraph.co.uk/technology/2020/04/05/china-floods-facebook-instagram-undeclared-coronavirus-propaganda/.

[98] World Health Organization, *Coronavirus disease (COVID-19): Serology*, Jun. 9, 2020, https://web.archive.org/web/20201105013101/https://www.who.int/news-room/q-a-detail/coronavirus-disease-covid-19-serology; Wikipedia, *Herd Immunity*, https://web.archive.org/web/20201230030556/https://en.wikipedia.org/wiki/Herd_immunity.

[99] @HuXijin_GT, Twitter, Mar. 14, 2020, https://twitter.com/HuXijin_GT/status/1238864397713305600.

[100] David Hutt, *Sweden-China ties grow ever icier over Hong Kong and coronavirus*, Nikkei Asia, Jun. 11, 2020, https://asia.nikkei.com/Politics/International-relations/Sweden-China-ties-grow-ever-icier-over-Hong-Kong-and-coronavirus.

[101] Leng Shumei, *Sweden's herd immunity strategy coldblooded, indifferent: netizens*, Global Times, Apr. 25, 2020, https://www.globaltimes.cn/content/1186720.shtml.

previous infection"—but on October 15, 2020, the WHO effectively erased the eons-long history of naturally-acquired immunity from its website:

> 'Herd immunity', also known as 'population immunity', is a concept used for vaccination, in which a population can be protected from a certain virus if a threshold of vaccination is reached.
>
> Herd immunity is achieved by protecting people from a virus, *not* by exposing them to it.[102] (emphasis added)

China's official spokesperson, Hua Chunying, posted a video of a 7-year-old girl reciting the importance of strict social distancing among children.[103] Simultaneously, hundreds of thousands of clandestine social media posts, which were later flagged as state-sponsored, expressed admiration for China's lockdowns and longed for governments around the world to emulate them, while denigrating governments and world leaders who failed to follow suit;[104] governments including, but not limited to: Nigeria,[105] Ghana,[106] South Africa,[107] Namibia,[108] Kenya,[109] France,[110] Spain,[111] Colombia,[112] Brazil,[113] Argentina,[114] Canada,[115] Australia,[116] India,[117] Germany,[118] the United Kingdom,[119] and the United States.[120] Not only is this very poor global citizenship, but especially in light of the dubious science discussed above, it's worth wondering whether these social media posts were intended to popularize lockdowns as the end in themselves.[121]

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[102] World Health Organization, *Coronavirus disease (COVID-19): Herd immunity, lockdowns and COVID-19*, Oct. 15, 2020, https://web.archive.org/web/20201214195732/https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19, *contra* World Health Organization, *Coronavirus disease (COVID-19): Serology*, Jun. 9, 2020, https://web.archive.org/web/20201105013101/https://www.who.int/news-room/q-a-detail/coronavirus-disease-covid-19-serology.

[103] @SpokespersonCHN, Twitter, Apr. 5, 2020, https://twitter.com/SpokespersonCHN/status/1246665952139198464.

[104] Raymond Zhong *et al.*, *Behind China's Twitter Campaign, a Murky Supporting Chorus*, N.Y. Times, Jun. 8, 2020, https://www.nytimes.com/2020/06/08/technology/china-twitter-disinformation.html.

[105] @Mr_Zaheed, Twitter, Mar. 16, 2020, https://twitter.com/Mr_Zaheed/status/1239494611497889795?s=20.

[106] @PolySarkcess, Twitter, Mar. 18, 2020, https://twitter.com/PolySarkcess/status/1240209649024016384.

[107] @SipheleleQalaba, Twitter, Mar. 22, 2020, https://twitter.com/SipheleleQalaba/status/1241634533176377344.

[108] @jaysibalatani, Twitter, Mar. 15, 2020, https://twitter.com/jaysibalatani/status/1239363614722621446?s=20.

[109] @King_Mindu, Twitter, Mar. 14, 2020, https://twitter.com/King_Mindu/status/1238765666053865473?s=20.

[110] @LDNSOM, Twitter, Mar. 15, 2020, https://twitter.com/LDNSOM/status/1239127435532255232?s=20.

[111] @juanitoalimagna, Twitter, Mar. 15, 2020, https://twitter.com/juanitoalimagna/status/1239154669743738881?s=20.

[112] @chez_art, Twitter, Mar. 15, 2020, https://twitter.com/chez_art/status/1239224144308420609?s=20.

[113] @dedeteodoro, Twitter, Mar. 14, 2020, https://twitter.com/dedeteodoro/status/1238914168251723779.

[114] @Loukasz_, Twitter, Mar. 19, 2020, https://twitter.com/Loukasz_/status/1240811202214875136.

[115] @yycjfl_yycguy, Twitter, Mar. 13, 2020, https://twitter.com/yycjfl_yycguy/status/1238481375356784640?s=20.

[116] @cxrdelias, Twitter, Mar. 16, 2020, https://twitter.com/cxrdelias/status/1239520104687099904?s=20.

[117] @DheerajShah_, Twitter, Mar. 15, 2020, https://twitter.com/DheerajShah_/status/1239202305976619009?s=2.

[118] @dirkregido, Twitter, Mar. 13, 2020, https://twitter.com/dirkregido/status/1238566874503413760?s=20.

[119] @DeanTweets_, Twitter, Mar. 25, 2020, https://twitter.com/DeanTweets_/status/1242829376447746049.

[120] @MoToTheMO94, Twitter, Mar. 16, 2020, https://twitter.com/MoToTheMO94/status/1239729692325773312.

When Italy became the first country outside China to lock down, Chinese experts arrived on March 12 and two days later advised a tighter lockdown: "There are still too many people and behaviors on the street to improve."[122] On March 19, they repeated that Italy's lockdown was "not strict enough." "Here in Milan, the hardest hit area by COVID-19, there isn't a very strict lockdown ... We need every citizen to be involved in the fight of COVID-19 and follow this policy."[123]

Chinese company DJI donated drones to 22 U.S. states to help enforce lockdown rules.[124] Months later, DJI was blacklisted by the U.S. for having "enabled wide-scale human rights abuses within China through abusive genetic collection and analysis or high-technology surveillance, and/or facilitated the export of items by China that aid repressive regimes ..."[125] On July 7, FBI Director Christopher Wray disclosed that the CCP even specifically approached local politicians to endorse its pandemic response:

> [W]e have heard from federal, state, and even local officials that Chinese diplomats are aggressively urging support for China's handling of the COVID-19 crisis. Yes, this is happening at both the federal and state levels. Not that long ago, we had a state senator who was recently even asked to introduce a resolution supporting China's response to the pandemic.[126]

China has financial stakes in virtually every top media outlet.[127] With regard to complex issues like lockdowns, China's influence can collectively tip these media entities in a dangerous direction, such as encouraging countries to copy China's response to COVID-19.[128] The CCP has shaped the media's scientific narratives by consistently promoting the falsehood that "China controlled the virus,"[129] which is, of course, a baldfaced lie.[130] Nonetheless, by encouraging mainstream publications to repeat the lie that "China controlled the virus," the CCP has normalized this lie and ensured its forged data remains integral to scientific discourse.[131] Meanwhile, the CCP began closely monitoring Chinese academic publications on COVID-19.[132]

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[121] Michael P. Senger, *China's Global Lockdown Propaganda Campaign*, Tablet, Sep. 15, 2020, https://www.tabletmag.com/sections/news/articles/china-covid-lockdown-propaganda.

[122] Huffington Post, *"Ci sono ancora troppe persone per strada e comportamenti da migliorare"*, Mar. 14, 2020, https://www.huffingtonpost.it/entry/ci-sono-ancora-troppe-persone-per-strada-e-comportamenti-da-migliorare_it_5e6cc3b5c5b6dda30fc9dcd0.

[123] James Patterson, *Italy Coronavirus Lockdown 'Not Enough,' Says China, Healthcare Staff Stop Counting Bodies*, Int'l Bus. Times, Mar. 20, 2020, https://www.ibtimes.com/italy-coronavirus-lockdown-not-enough-says-china-healthcare-staff-stop-counting-2943402.

[124] Zachary Evans, *Chinese Company Suspected of Spying on U.S. Citizens Donates Police Drones to 22 States*, Nat'l Review, Apr. 20, 2020, https://www.nationalreview.com/news/chinese-company-suspected-of-spying-on-u-s-citizens-donates-police-drones-to-22-states/.

[125] Bureau of Industry and Security, *Addition of Entities to the Entity List, Revision of Entry on the Entity List, and Removal of Entities from the Entity List*, U.S. Dep't of Commerce, 15 CFR 744 Docket No. 201215-0347, Dec. 22, 2020, https://public-inspection.federalregister.gov/2020-28031.pdf.

[126] Christopher Wray, *The Threat Posed by the Chinese Government and the Chinese Communist Party to the Economic and National Security of the United States*, FBI, Jul. 7, 2020, https://www.fbi.gov/news/speeches/the-threat-posed-by-the-chinese-government-and-the-chinese-communist-party-to-the-economic-and-national-security-of-the-united-states

[127] Chrissy Clark, *A Rundown Of Major U.S. Corporate Media's Business Ties To China*, The Federalist, May 4, 2020, https://thefederalist.com/2020/05/04/has-china-compromised-every-major-mainstream-media-entity/.

The significance of China's global lockdown propaganda campaign is the intent behind it. While the scientific issues described above—criminal negligence by the WHO, alarmist mortality models, dubious PCR tests, and bad studies on asymptomatic transmission—could theoretically be attributed to incompetence, the CCP's propaganda is evidence of deliberation. Sloppy science may be professionally shameful, but it is neither a crime nor a moral failing. The possibility of corruption and fraud, on the other hand, is another matter.

8. Many Prominent Pro-Lockdown Scientists Show Conspicuous Pro-China Bias

Not only were lockdowns laundered into science with a shocking lack of scientific debate, but many scientists have shown an unusual deference to China in evaluating the continuation of lockdown policies. These scientists have continuously praised China, and many appear to be operating on the assumption that China has, in fact, eliminated domestic COVID-19 cases as the CCP claims, when in fact this claim is a lie, as confirmed by the intelligence community.[133] Needless to say, promoting major public policy decisions based on this mistaken assumption can have devastating consequences.

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[128] Donald G. McNeil Jr., *To Take On the Coronavirus, Go Medieval on It*, N.Y. Times, Feb. 28, 2020, https://www.nytimes.com/2020/02/28/sunday-review/coronavirus-quarantine.html; Gerry Shih, *Locked down in Beijing, I watched China beat back the coronavirus*, Wash. Post, Mar. 16, 2020, https://www.washingtonpost.com/world/asia_pacific/locked-down-in-beijing-i-watched-china-beat-back-the-coronavirus/2020/03/16/f839d686-6727-11ea-b199-3a9799c54512_story.html; David Brennan, *Should Trump Copy China's Aggressive Coronavirus Strategy?*, Newsweek, Mar. 12, 2020, https://www.newsweek.com/should-donald-trump-copy-china-aggressive-coronavirus-strategy-covid-19-outbreak-1491909.

[129] Peter Hessler, *How China Controlled the Coronavirus*, New Yorker, Aug. 10, 2020, https://www.newyorker.com/magazine/2020/08/17/how-china-controlled-the-coronavirus.

[130] Keith Naughton, *Coronavirus: It's time to get real about the misleading data*, The Hill, Apr. 1, 2020, https://thehill.com/opinion/technology/490541-coronavirus-its-time-to-get-real-about-the-misleading-data.

[131] Kaylee McGhee White, *Don't trust China's coronavirus numbers*, Wash. Exam'r, Mar. 30, 2020, https://www.washingtonexaminer.com/opinion/dont-trust-chinas-coronavirus-numbers; Michael Meyer-Resende, *How reliable is WHO coronavirus data?*, EU Observer, Mar. 19, 2020, https://euobserver.com/opinion/147776.

[132] Stephanie Kirchgaessner *et al.*, *China clamping down on coronavirus research, deleted pages suggest*, The Guardian, Apr. 11, 2020, https://www.theguardian.com/world/2020/apr/11/china-clamping-down-on-coronavirus-research-deleted-pages-suggest.

[133] Sonam Sheth and Isaac Scher, *The US intelligence community has reportedly concluded that China intentionally misrepresented its coronavirus numbers*, Business Insider, Apr. 1, 2020, https://www.businessinsider.com/us-intelligence-found-china-misrepresented-coronavirus-stats-report-2020-4.

In a May 2020 interview for China Central Television, Richard Horton, editor-in-chief of the esteemed medical journal The Lancet, emphatically praised China's lockdowns:

> It was not only the right thing to do, but it also showed other countries how they should respond in the face of such an acute threat. So, I think we have a great deal to thank China for ...[134]

In July, Horton reiterated his gratitude toward China, tweeting: "Indeed. China should not be 'blamed'. In my view, we should thank Chinese scientists and health workers for their incredibly selfless commitment to attacking this outbreak. They deserve our unconditional gratitude."[135] And in August, Horton doubled down again in a full-throated piece that had surprisingly little to do with health:

> The "century of humiliation," when China was dominated by a colonially-minded west and Japan, only came to an end with the Communist victory in the civil war in 1949 ... Every contemporary Chinese leader, including Xi Jinping, has seen their task as protecting the territorial security won by Mao and the economic security achieved by Deng.[136]

On October 8, the Lancet published a ringing endorsement of China's pandemic response: *China's successful control of COVID-19.*[137] This article was met with high praise by Chen Weihua, China Daily EU Bureau Chief:

> Despite ignorance by many in the West, this article by The Lancet is a powerful endorsement of China's successful pandemic response. Hate to read stories by those paparazzi journalists who are experts at spinning but have little knowledge of science.[138]

Chinese scientists later submitted an article to The Lancet arguing that SARS-CoV-2 originated in India, in the midst of ongoing border skirmishes with India.[139] Just weeks later, however, the party line changed again amid economic tensions with Australia, and Global Times claimed the coronavirus may have come from Australia.[140]

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[134] Global Times, *China shows world the right way for pandemic response: The Lancet chief editor*, May 2, 2020, https://www.globaltimes.cn/content/1187265.shtml.

[135] @richardhorton1, Twitter, Jul. 7, 2020, https://twitter.com/richardhorton1/status/1280617079960371200.

[136] Richard Horton, *This wave of anti-China feeling masks the west's own Covid-19 failures*, The Guardian, Aug. 3, 2020, https://www.theguardian.com/commentisfree/2020/aug/03/covid-19-cold-war-china-western-governments-international-peace.

[137] Talha Burki, *China's successful control of COVID-19*, The Lancet Vol. 20(11), Oct. 8, 2020, https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30800-8/fulltext.

[138] @chenweihua, Twitter, Oct. 16, 2020, https://twitter.com/chenweihua/status/1317014216532963330.

[139] Shen Libing *et al.*, *The Early Cryptic Transmission and Evolution of SARS-CoV-2 in Human Hosts*, SSRN, Nov. 16, 2020, https://europepmc.org/article/ppr/ppr241540.

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William A. Haseltine, Chairman of the Board of the US-China Health Summit since 2015, has also reserved great praise for China. In October 2020, China Daily syndicated a column from Haseltine in which he towed the CCP's party line on Sweden, chastising the country for choosing to "forego lockdowns" and base its strategy on "herd immunity," for which he erroneously states that Sweden's "COVID-19 infection and fatality rates were among the world's highest":

> But to base a pandemic-response strategy on the assumption that herd immunity is inevitable—vaccine or no vaccine—is to afford a virus a path of least resistance. That was the case in Sweden, where policymakers decided to forego lockdowns and business closures in favor of more lenient advisories on mask-wearing and social distancing. Unsurprisingly, Sweden's subsequent COVID-19 infection and fatality rates were among the world's highest.[141]

Early in the pandemic, on March 25, Haseltine also praised China's measures in contrast to the United States, most of which had yet to impose lockdowns: "The measures the US is taking to control Covid-19 are far inferior to what was done in China according to @JNBPage in @WSJ - http://ow.ly/BS5R50yVDV2. For more details see an interview quarantine of an American in Shanghai - http://ow.ly/nz3050yVDXO."[142] Later that day, Haseltine continued: "Two months of lockdown in Hubei province in China has been lifted, although Wuhan remains under quarantine until April 8. This is an important moment, and testament to the effectiveness of containment measures."[143] Haseltine praised China again on May 20: "It is possible to eliminate Covid without effective drugs or vaccines. This is how they did it in Wuhan, China."[144]

On June 4, Haseltine again compared the U.S. negatively to China: "The steps China has taken to protect its population through testing and tracking is truly impressive. The US, on the other hand, is failing."[145] And again on September 15: "Has the US has done [sic] all it can to control Covid-19? Covid can be contained without a vaccine or drug. China now has near zero new infections. ACCESS Health & the @RockefellerFdn explored how they did it with the use of digital technologies. http://ow.ly/I4Ch50BrEpJ."[146]

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[140] Charlie Moore, *China claims coronavirus may have started in AUSTRALIA and travelled to Wuhan's wet market via frozen steak exports - and attacks US alliance with insulting new cartoon*, Daily Mail Australia, Dec. 6. 2020, https://www.dailymail.co.uk/news/article-9024311/China-claims-coronavirus-started-AUSTRALIA.html.

[141] William A. Haseltine, *Herd immunity will not defeat COVID-19*, China Daily, Oct. 12, 2020, https://global.chinadaily.com.cn/a/202010/12/WS5f8392dba31024ad0ba7df2a.html; Worldometer, *COVID-19 Coronavirus Pandemic*, http://web.archive.org/web/20201012071325/https://www.worldometers.info/coronavirus/.

[142] @WmHaseltine, Twitter, Mar. 25, 2020, https://twitter.com/WmHaseltine/status/1242870021422034944?s=20.

[143] @WmHaseltine, Twitter, Mar. 25, 2020, https://twitter.com/WmHaseltine/status/1242887061310443521?s=20.

[144] @WmHaseltine, Twitter, May 20, 2020, https://twitter.com/WmHaseltine/status/1263158816365064194?s=20.

[145] @WmHaseltine, Twitter, Jun. 4, 2020, https://twitter.com/WmHaseltine/status/1268578282573889539?s=20.

Tom Frieden, former director of the CDC, is another prominent advocate of COVID-19 lockdowns. In 2015, "Frieden praised the public health partnership between China and the United States," according to Global Times.[147] In 2017, Frieden joined China in backing Tedros Adhanom as director of the WHO over the United Kingdom's eminently-qualified David Nabarro: "Tedros is an excellent choice to lead WHO. He succeeded in Ethiopia, making remarkable health progress…"[148] To the contrary, as was widely-known at the time, Tedros had helped Ethiopia's regime cover up three cholera epidemics during his time as Ethiopia's Minister of Public Health.[149] As a senior member of the Tigray People's Liberation Front (TPLF), designated a terrorist organization by the United States in the 1990s, Tedros "was a crucial decision maker in relation to security service actions that included killing, arbitrarily detaining and torturing Ethiopians" and was "personally responsible for brutal repression of the Amhara people, using aid money selectively to starve them out and deny them access to basic services," —war crimes for which charges of genocide have recently been submitted against him at the International Criminal Court at the Hague.[150]

Frieden traveled extensively throughout China in 2018 and 2019 for public health collaborations, and he has heaped praise on China since the COVID-19 crisis began.[151] Frieden praised China's response early on, writing for CNN on February 25: "China's extraordinary cordon of Hubei province and other areas bought the world at least a month of lead time to prepare."[152] In an April interview, Frieden told China Global Television (CGTN): "There's a lot the world can learn from China on stopping COVID-19."[153]

On March 17, Frieden urged the U.S. to emulate China's expansion of hospital capacity: "When @voxdotcom posted this yesterday I thought hospitals might need to triple their beds and ventilators for pts with #COVID19. Now data suggests we may need as much as 10x more. China built 1K bed hospitals in 8 days, urgent action needed in US now."[154]

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[146] @WmHaseltine, Twitter, Sep. 15, 2020, https://twitter.com/WmHaseltine/status/1305927462795214851?s=20.

[147] Xinhua, *China, US eye cooperation in fighting global epidemic diseases*, Global Times, May 13, 2015, https://www.globaltimes.cn/content/921533.shtml.

[148] Helen Branswell, *WHO elects Ethiopia's Tedros Adhanom Ghebreyesus as its new director general*, Stat, May 23, 2017, https://www.statnews.com/2017/05/23/who-director-general-tedros/.

[149] Donald G. McNeil Jr., *Candidate to Lead the W.H.O. Accused of Covering Up Epidemics*, N.Y. Times, May 13, 2017, https://www.nytimes.com/2017/05/13/health/candidate-who-director-general-ethiopia-cholera-outbreaks.html.

[150] Jonathan Ames, *Tedros Adhanom: WHO chief may face genocide charges*, The Times of London, Dec. 14, 2020, https://www.thetimes.co.uk/article/who-chief-tedros-adhanom-ghebreyesus-may-face-genocide-charges-2fbfz7sff; Frank Report, *The Ethiopian Terrorist in Charge of the World Health Organization — Dr. Tedros Adhanom*, Apr. 14, 2020, https://frankreport.com/2020/04/14/the-ethiopian-terrorist-in-charge-of-the-world-health-organization-dr-tedros-adhanom/.

[151] @DrTomFrieden, Twitter, Nov. 7, 2018, https://twitter.com/DrTomFrieden/status/1060229543762554881?s=20; @DrTomFrieden, Twitter, Jun. 21, 2019, https://twitter.com/DrTomFrieden/status/1142073802723119109?s=20.

[152] Dr. Tom Frieden, *Former CDC director: A coronavirus pandemic is inevitable. What now?*, CNN, Feb. 25, 2020, https://www.cnn.com/2020/02/25/health/coronavirus-pandemic-frieden/index.html.

[153] @cgtnamerica, Twitter, Apr. 8, 2020, https://twitter.com/cgtnamerica/status/1248028432618999808.

On April 1, Frieden tweeted the same words three times, praising China and urging the U.S. to ramp up its response: "I'm angry. Friends & neighbors sick & dying. 2.9: days Wuhan's action bought China: https://bit.ly/3bCxFJg. 2.9: number of MONTHS squandered by US not ramping up protection of HCW, critical care, testing, contact tracing, isolation, quarantine. Roadmap: https://bit.ly/2R3RtgW."[155]

In August, Frieden praised China several times, contrasting its "success" with that of the U.S. On August 10: "Meanwhile in China. They report they can now do 4.8M PCR tests/day. Schools are opening and staying open. Mask-wearing is, where appropriate, nearly universal. Last week, they had an average of 34 cases/day. That's a case rate less than 1/5,000th that of the US."[156] On August 15: "This reflection from an American teaching in Chengdu—where Covid lockdowns were strictly enforced—examines the nuances of life in China and how the country was able to crush the curve."[157] And on August 16: "Thoughts about huge, unmasked crowds at festivals in Wuhan!? Well, that's the reward for crushing the curve - you get back to near pre-Covid reality. But that's probably not a reasonable goal for most places, where simmering control is a realistic best-case scenario."[158] And on August 18: "China reported a case rate less than 1/5,000th of the US'. It's possible for us to control Covid too if Americans work together and fully support public health."[159]

While these individuals are unique in their pro-China, pro-lockdown bias, as scientists they're far from alone in their apparent ties to the CCP. In June, the National Institutes of Health (NIH) disclosed that 189 of its grantees had received undisclosed funding from foreign governments.[160] In 93% of cases, including that of Charles Lieber, chair of Harvard's chemistry department, the undisclosed funding came from China.[161] The co-founders of CanSino Biologics, a Chinese vaccine company collaborating with Canada, were found to be members of the CCP's Thousand Talents Plan for co-opting and incentivizing scientists to transfer research and knowledge to China.[162] According to the Harvard Crimson, the largest gift in the history of Harvard's Chan School of Public Health came in part from a "pawn of the CCP," a "cheerleader for a government responsible for significant humanitarian crises" through a series of shell companies, the largest of which was named in the Panama Papers.[163]

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[154] @DrTomFrieden, Twitter, Mar. 17, 2020, https://twitter.com/DrTomFrieden/status/1239988987604983808?s=20.

[155] @DrTomFrieden, Twitter, Apr. 1, 2020, https://twitter.com/DrTomFrieden/status/1245428638809575425?s=20; @DrTomFrieden, Twitter, Apr. 1, 2020, https://twitter.com/DrTomFrieden/status/1245428166413484033?s=20; @DrTomFrieden, Twitter, Apr. 1, 2020, https://twitter.com/DrTomFrieden/status/1245427587440148480?s=20.

[156] @DrTomFrieden, Twitter, Aug. 14, 2020, https://twitter.com/DrTomFrieden/status/1294339295747215362.

[157] @DrTomFrieden, Twitter, Aug. 15, 2020, https://twitter.com/DrTomFrieden/status/1294787213331398657?s=20.

[158] @DrTomFrieden, Twitter, Aug. 18, 2020, https://twitter.com/DrTomFrieden/status/1295773328523825158?s=20.

[159] @DrTomFrieden, Twitter, Aug. 18, 2020, https://twitter.com/DrTomFrieden/status/1295777614016262145?s=20.

[160] Jeffrey Mervis, *Fifty-four scientists have lost their jobs as a result of NIH probe into foreign ties*, Science, Jun. 12, 2020, https://www.sciencemag.org/news/2020/06/fifty-four-scientists-have-lost-their-jobs-result-nih-probe-foreign-ties.

[161] Office of Public Affairs, *Harvard University Professor and Two Chinese Nationals Charged in Three Separate China Related Cases*, U.S. Dep't of Justice Press Release No. 20-99, Jan. 28, 2020,

There is nothing immoral or illegal about merely being wrong. But given the magnitude of the decisions being made during the COVID-19 crisis, if even a handful of influential scientists are cross-incentivized to support lockdowns regardless of any real data or results, this can have an outsized impact on both public opinion and policy.

9. Many Other Influential Lockdown Supporters Are Both Woefully Unqualified to Be Advising World Leaders on Pandemic Policy and Often Show Conspicuous Pro-China Bias

In addition to the many scientists with ties to China, a number of woefully unqualified individuals have held themselves out to the public and politicians as experts with regard to COVID-19 epidemiology and lockdowns, when in fact their backgrounds reveal them to have no such expertise. Many of these, too, have shown unusual deference to China.

On January 25, 2020, Eric Feigl-Ding, an epidemiologist in Harvard's nutrition department with little background in infectious disease, wrote, "HOLY MOTHER OF GOD, the new coronavirus is a 3.8!!! How bad is that reproductive R0 value? It is thermonuclear pandemic level bad."[164] This was the first of a months-long series of dubious, but widely-shared, alarmist tweets by the previously unknown Ding, by virtue of which he gained hundreds of thousands of Twitter followers and became one of the leading advocates of strict COVID-19 mandates, despite his evident lack of qualifications.[165]

Ding is an alumnus of the World Economic Forum's Global Shapers, a group of young people that considers Taiwan a part of Greater China[166] and has campaigned during the COVID-19

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https://www.justice.gov/opa/pr/harvard-university-professor-and-two-chinese-nationals-charged-three-separate-china-related.

[162] Sam Cooper, *Chinese vaccine company executives worked in program now targeted by Western intelligence agencies*, Global News, Dec. 2, 2020, https://globalnews.ca/news/7483970/cansino-nrc-covid-vaccine/.

[163] Guillermo S. Hava, *The Other Chan: Donation Sanitization at the School of Public Health*, The Harvard Crimson, Oct. 19, 2020, https://www.thecrimson.com/column/for-sale/article/2020/10/19/hava-the-other-chan/.

[164] @DrEricDing, Twitter, Jan. 25, 2020, https://threader.app/thread/1220919589623803905.

[165] Tom Bartlett, *This Harvard Epidemiologist Is Very Popular on Twitter. But Does He Know What He's Talking About?*, The Chronicle of Higher Educ., Apr. 17, 2020, https://www.chronicle.com/article/this-harvard-epidemiologist-is-very-popular-on-twitter-but-does-he-know-what-hes-talking-about/.

[166] Global Shapers Community, *Taipei Hub*, http://web.archive.org/web/20201024004411/https://www.globalshapers.org/hubs/taipei-hub.

crisis to share "their personal experiences of combating the coronavirus in their cities and of adapting to a new normal."[167] His enormous Twitter following irked many of his colleagues, prompting prominent Harvard epidemiologist Marc Lipsitch to denounce him as a charlatan: "OK lots of people think this is an intramural tiff. In the sense that we have been working @CCDD_HSPH for a decade and at @HarvardEpi for 25y to establish ID epidemiology as a field of excellence & we don't like a charlatan exploiting a tenuous connection for self-promotion, yes."[168]

Columbia virologist Angela Rasmussen agreed with Dr. Lipsitch's assessment: "Eric Feigl-Ding is a charlatan. If Dr. Lipsitch sounds condescending, it's because EFD has repeatedly claimed expertise he doesn't have in order to get attention. He sensationalizes data and distributes outright misinformation. He's harmful to public health and I disdain that too."[169]

These denunciations by Drs. Rasmussen and Lipsitch are noteworthy in that both have supported limited lockdowns and criticized both pro- and anti-lockdown scientists and commentators. However, their denunciations of Ding have not slowed down his Twitter campaign, and he has continued to present himself in attire worn by a medical doctor, completely inappropriate to his background as a nutritionist.[170]

Tomas Pueyo is an engineer and MBA with no background in health or epidemiology who came to sudden fame for a March 10 article on the self-publishing site Medium titled "Coronavirus: Why You Must Act Now," in which he implored leaders around the world to implement lockdowns on China's model to counter rising COVID-19 cases. "The total number of cases grew exponentially *until China contained it*. But then, it leaked outside, and now it's a pandemic that nobody can stop."[171] (emphasis added)

Pueyo's article quickly went viral and was shared hundreds of thousands of times, including by many celebrities.[172] After it went viral, Pueyo went on tour advising state legislators on implementing lockdowns.[173]

Not only was Pueyo unqualified to be dispatching this type of epidemiological advice to world leaders, but Pueyo's March 10 article contains a number of red flags. First, Pueyo several times refers to the coronavirus as a "pandemic." However, as of March 10, the WHO had not yet declared the coronavirus a pandemic,[174] and per the article, cases accounted for less than 0.0015% of the world's population. In the article, Pueyo then goes on to implore leaders:

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[167] World Economic Forum, *Global Shapers Community Annual Report 2019–2020*, https://weforum.ent.box.com/v/gsc-report-2020.
[168] @mlipsitch, Twitter, Mar. 19, 2020, https://twitter.com/mlipsitch/status/1240846136589660165.
[169] @angie_rasmussen, Twitter, Apr. 14, 2020, https://twitter.com/angie_rasmussen/status/1250240307037233153.
[170] @DrEricDing, Twitter, Oct. 20, 2020, https://twitter.com/DrEricDing/status/1318693240309223424.
[171] Tomas Pueyo, *Coronavirus: Why You Must Act Now*, Medium, Mar. 10, 2020, https://tomaspueyo.medium.com/coronavirus-act-today-or-people-will-die-f4d3d9cd99ca.
[172] @sapinker, Twitter, Mar. 11, 2020, https://twitter.com/sapinker/status/1237761514989289472.
[173] @tomaspueyo, Twitter, Mar. 25, 2020, https://twitter.com/tomaspueyo/status/1242711009254506497?s=20.

> But in 2–4 weeks, when the *entire world* is in lockdown, when the few precious days of social distancing you will have enabled will have saved lives, people won't criticize you anymore: They will thank you for making the right decision. (emphasis added)

Not only was the coronavirus not yet a pandemic, but as of March 10 there were fewer than 200 cases in the entire developing world outside China. Pueyo had no good reason to call the coronavirus a pandemic, no good reason to believe the *entire world* would be in lockdown in two to four weeks, and, above all, no good reason to be advising world leaders to lock down.

On March 19, Pueyo posted another Medium article titled "The Hammer and Dance," which again went viral, explaining the strategy Pueyo described as "the Hammer"—quick, aggressive lockdowns when outbreaks occur—followed by "the Dance"—tracing, surveillance, and quarantine measures.[175]

On March 22, three days after Pueyo's "The Hammer and Dance" was published, a strategy paper by the German Federal Ministry of the Interior (BMI) entitled "How to get a grip on COVID-19" (later dubbed "the Panic Paper") was secretly distributed to members of German parliament and leaders of certain media outlets—this paper played an outsized role in encouraging the German government to implement a nationwide lockdown in March.[176] After the BMI refused to release the Panic Paper to the public under the Freedom of Information Act, it was leaked by FragDenStaat, a whistleblower site.[177]

Despite being published just three days after Pueyo's article, the Panic Paper relied heavily on Pueyo's work, referring to the strategy of intermittent lockdowns and surveillance as the "Hammer and Dance" without citing Pueyo. The term "Hammer and Dance" has no history in epidemiology—Tomas Pueyo invented it for his March 19 article.[178]

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[174] World Health Organization, *Archived: WHO Timeline - COVID-19*, Apr. 27, 2020, https://www.who.int/news/item/27-04-2020-who-timeline---covid-19.

[175] Tomas Pueyo, *Coronavirus: The Hammer and the Dance*, Medium, Mar. 19, 2020, https://tomaspueyo.medium.com/coronavirus-the-hammer-and-the-dance-be9337092b56.

[176] Parliamentwatch, *Das interne Strategiepapier des Innenministeriums zur Corona-Pandemie*, Apr. 7, 2020, https://www.abgeordnetenwatch.de/blog/informationsfreiheit/das-interne-strategiepapier-des-innenministeriums-zur-corona-pandemie.

[177] Federal Ministry of the Interior, Building and Community, *Wie wir COVID-19 unter Kontrolle bekommen, Strategiepapier des Bundesinnenministeriums*, FragDenStaat, Mar. 22, 2020, https://fragdenstaat.de/dokumente/4123-wie-wir-covid-19-unter-kontrolle-bekommen/.

[178] Google Trends, *Hammer and Dance*, https://web.archive.org/web/20201230074513if_/https://trends.google.com/trends/explore?date=all&q=%22hammer%20and%20dance%22; Google Trends, *Hammer and the Dance*,

Otto Kölbl is one of the authors of the Panic Paper.[179] Kölbl has been "researching socio-economic development in China and (comparatively) in other developing countries as well as their presentation in the Western media" since 2007.[180] From 2005 to 2006 he was a language teacher at Northwestern Polytechnical University in Xi'an, China. He now runs his own blog called "rainbowbuilders.org" in which he has described Hong Kong as "parasitic"[181] and praised China's exemplary development of Tibet.[182] Like Pueyo, Kölbl is extraordinarily unqualified to be advising world leaders on any aspect of epidemiology, infectiology, or public health, fields in which he has no background.

Maximilian Mayer is another co-author of the Panic Paper.[183] Mayer taught at the University of Nottingham in Ningbo China and Tongji University in Shanghai, and was a research fellow at Renmin University Beijing.[184] Mayer's research interests include China's foreign and energy policy, climate politics, and international relations, and he edited *Rethinking the Silk-Road: China's Belt and Road Initiative and Emerging Eurasian Relations.*[185] He has since returned to Bonn University as a junior professor of international relations.[186] Like Pueyo and Kölbl, Mayer lacks any apparent qualification in epidemiology, infectiology, or public health, the fields on which he advised Germany's leaders via the Panic Paper.

From the earliest possible date, physicist Yaneer Bar-Yam has urged the entire world to emulate China's strategy of attempting to eliminate COVID-19 entirely through the adoption of strict social distancing measures. On February 2, Bar-Yam praised China's supposed rapid construction of a hospital: "Hospital built in days in China is now operational."[187] On February 28, Bar-Yam quoted the WHO's report from its China Joint Mission which sent the world into

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https://web.archive.org/web/20201230074618if_/https://trends.google.com/trends/explore?date=all&q=%22hammer%20and%20the%20dance%22.

[179] Federal Ministry of the Interior, Building and Community, *Brief: Informationsfreiheitsgesetz Strategiepapier des Bundesinnenministeriums "Wie wir COVID-19 unter Kontrolle bekommen"*, Jun. 9, 2020, https://clubderklarenworte.de/wp-content/uploads/2020/06/BMI-Dokument-incl.-Autoren.pdf.

[180] Université de Lausanne Faculté des lettres Section d'allemand, *Kölbl Otto*, https://web.archive.org/web/20201230040127/https://www.unil.ch/all/fr/home/menuinst/mitarbeitende-1/assoziierte-mitarbeitende/kolbl-otto.html.

[181] Otto Kölbl, *Hong Kong – An extreme example of parasitic development*, https://web.archive.org/web/20201230040346/http://rainbowbuilders.org/china-development/hong-kong-economy.

[182] Otto Kölbl, *Have Tibetans benefited from recent economic development?*, https://web.archive.org/web/20201230040016/http://rainbowbuilders.org/tibet-development/tibet-development-aid.

[183] Federal Ministry of the Interior, Building and Community, *Brief: Informationsfreiheitsgesetz Strategiepapier des Bundesinnenministeriums "Wie wir COVID-19 unter Kontrolle bekommen"*, Jun. 9, 2020, https://clubderklarenworte.de/wp-content/uploads/2020/06/BMI-Dokument-incl.-Autoren.pdf.

[184] Munich Center for Technology in Society Technical University of Munich, *Dr. Maximilian Mayer*, https://web.archive.org/web/20201230034459/https://www.mcts.tum.de/en/people/maximilian-mayer/.

[185] *Id.*

[186] Universität Bonn Institut für Politische Wissenschaft und Soziologie, *Jun.-Prof. Dr. Maximilian Mayer*, https://web.archive.org/web/20201230034212/https://www.politik-soziologie.uni-bonn.de/de/personal/jun.-prof.-maximilian-mayer.

[187] @yaneerbaryam, Twitter, Feb. 2, 2020, https://twitter.com/yaneerbaryam/status/1224050641443704838?s=20.

lockdown: "China's uncompromising and rigorous use of non-pharmaceutical measures to contain transmission of the COVID-19 virus in multiple settings provides vital lessons for the global response."[188] That same day, Bar-Yam continued "We should all acknowledge and thank China for their aggressive response to the Wuhan coronavirus. This includes stopping almost all travel of their citizens to the world to prevent contagion elsewhere."[189] In February, Bar-Yam launched the website www.endcoronavirus.org, which was quickly translated into 17 languages, urging countries around the world to implement Wuhan-style lockdowns.[190]

Bar-Yam has spent the better part of a year admiring China's lockdowns—including the CCP's murderous lockdown in Xinjiang—and promoting the use of China's data despite allegations of fraud. On July 18, Bar-Yam praised China's "wartime" lockdown in Xinjiang: "17 new cases, shut the city down. Don't give it a chance. China coronavirus: 'Wartime state' declared for Urumqi in Xinjiang."[191] This same lockdown simultaneously caused tremendous concern among human rights watchers and activists due to the CCP's concomitant acts of genocide in Xinjiang against Uyghur Muslims and other Turkic minorities.[192]

On March 8, Bar-Yam defended China's data, in contrast to the U.S.: "Actually, the numbers in the US are underreported because of limited testing. This is known. Many said the numbers in China are underreported, nobody has shown evidence. If you have it show it or take a seat."[193] Bar-Yam reiterated this sentiment on March 14: "Speculations about the problems in China with data are projections."[194] On March 29, Bar-Yam encouraged the U.S. to emulate China: "We need a much wider restriction. Still, China used such a strategy effectively."[195] And, on August 3, Bar-Yam congratulated China: "Successful outbreak response: China's manufacturing activity surges in July."[196]

During crises, citizens trust experts with major policy decisions. For individuals to hold themselves out to the public and their leaders as experts in a crisis when they lack the necessary qualifications is bad enough; if they are somehow cross-incentivized to do so, it's much worse.

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[188] @yaneerbaryam, Twitter, Feb. 28, 2020, https://twitter.com/yaneerbaryam/status/1233386860958887936?s=20.
[189] @yaneerbaryam, Twitter, Feb. 28, 2020, https://twitter.com/yaneerbaryam/status/1233388113512292354?s=20.
[190] @yaneerbaryam, Twitter, Apr. 26, 2020, https://twitter.com/yaneerbaryam/status/1254455465200816134?s=20.
[191] @yaneerbaryam, Twitter, Jul. 18, 2020, https://twitter.com/yaneerbaryam/status/1284585257761734656?s=20.
[192] @SophieHRW, Twitter, Jul. 18, 2020, https://twitter.com/SophieHRW/status/1284566661597671425?s=20.
[193] @yaneerbaryam, Twitter, Mar. 8, 2020, https://twitter.com/yaneerbaryam/status/1236803093561520131?s=20.
[194] @yaneerbaryam, Twitter, Mar. 14, 2020, https://twitter.com/yaneerbaryam/status/1238828417187012610?s=20.
[195] @yaneerbaryam, Twitter, Mar. 29, 2020, https://twitter.com/yaneerbaryam/status/1244115730129465345?s=20.
[196] @yaneerbaryam, Twitter, Aug. 3, 2020, https://twitter.com/yaneerbaryam/status/1290153813903577088?s=20.

10. Several Top National Health Officials Among the Nations Are Woefully Unqualified and Show Conspicuous Pro-China Bias

Canada's top health minister, Patty Hajdu, has no apparent background in infectiology or epidemiology, her only public health experience being in substance abuse and injury prevention.[197] Hajdu's admiration for China goes back some time—in 2014 she advised: "Don't believe everything you read. Chinese sunset story pure propaganda," sharing an article arguing that stories of China broadcasting a sunset in Beijing were false.[198] Hajdu first earned the praise of Chinese foreign spokesperson Hua Chunying in early February 2020 for refusing to ban travel from China: "Canada believes the ban of entry has no basis, which is a sharp contrast for the U.S. behaviours."[199]

In April, Hajdu defended China's COVID-19 case data: "There is no indication the data that came out of China in terms of their death rate and infection rate was falsified in any way."[200] When a reporter pointed out a U.S. intelligence report to the contrary, Hajdu scolded: "I would say your question is feeding into conspiracy theories that many people have been perpetuating on the internet."[201] After that early April exchange, Hajdu was excoriated in Canada's press for "effectively trying to gaslight her own citizens about the conduct of a habitually oppressive and untruthful regime."[202] But Hajdu ignored that coverage and quickly doubled down just one month later, praising China's "historic containment efforts."[203]

Hajdu continued into September, again earning aplomb from CGTN for defending China: "very early on China alerted the World Health Organization to the emergence of a novel coronavirus and also shared the sequencing of the gene which allowed countries to be able to rapidly produce tests to be able to detect it in their own countries."[204] For this, Chen Weihua, China Daily EU

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[197] Joan Bryden, *Nothing prepared Patty Hajdu for this*, Canada's Nat'l Observer, Apr. 6 2020, https://www.nationalobserver.com/2020/04/06/features/nothing-prepared-patty-hajdu.

[198] @PattyHajdu, Twitter, Jan. 20, 2014, https://twitter.com/PattyHajdu/status/425431767290376192?s=20.

[199] Christy Somos, *China praises Canada, slams U.S. over coronavirus response*, CTV News, Feb. 3, 2020, https://www.ctvnews.ca/world/china-praises-canada-slams-u-s-over-coronavirus-response-1.4795270.

[200] Graeme Wood, *Questioning WHO and China virus data feeds conspiracy theories: Health Minister*, Richmond News, Apr. 2, 2020, https://web.archive.org/web/20200409133450/https://www.richmond-news.com/questioning-who-and-china-virus-data-feeds-conspiracy-theories-health-minister-1.24111603.

[201] *Id.*

[202] Robyn Urback, *Canadians have been gaslit on China*, The Globe and Mail, Apr. 30, 2020, https://www.theglobeandmail.com/opinion/article-canadians-have-been-gaslit-on-china/.

[203] True North, *Hajdu stands by praise for Chinese government and wanting to keep borders open*, Apr. 30, 2020, https://tnc.news/2020/04/30/hajdu-stands-by-praise-for-chinese-government-and-wanting-to-keep-borders-open/.

[204] CGTN, *Canada's health minister praises China's handling of COVID-19*, Sep. 16, 2020, https://news.cgtn.com/news/2020-09-16/Canada-s-health-minister-praises-China-s-handling-of-COVID-19--TPrDfplKJq/index.html.

Bureau Chief, praised Hajdu: "Canadian Health Minister Hajdu is a role model. She is a disappointment to those paparazzi journalists and fearmongers."[205]

Hajdu even earned a special nod from China's Ministry of Foreign Affairs: "We noticed relevant reports and applaud the Canadian health minister's objective and fair remarks."[206]

As commentator Spencer Fernando pointed out, "Propaganda Patty … appears to be one of the only people on Earth who actually believes China's official virus numbers."[207] Apparently unrepentant, Hajdu again scolded a journalist questioning data, echoing her April sentiments: "Mr. Speaker, do you know what will help Canadians' lives? If the member opposite and the leader of the opposition stop their members from sharing fake and dangerous news like the member from Lethridge and the member of Carleton stay focused on saving lives of Canadians instead of spreading conspiracy theories."[208]

Matt Hancock is a former economist and civil servant who had little to no background in public health or natural science before becoming health secretary of the United Kingdom. Prior to COVID-19, Hancock reportedly showed little interest in his role: "For him, it's all about promoting himself and using it as a stepping stone to his next job," said another NHS chief. "Tech is the only area in which he's made a mark… But his belief that tech can solve many of the NHS's difficulties had led to him being derided by people he needs to respect him."[209]

Hancock has been especially keen on the adoption of technology from China, meeting with Kai-Fu Lee, CEO of Chinese venture capital firm Sinovation Ventures, in January 2018.[210] (In 2019, Kai-Fu Lee became part of the World Economic Forum's AI Council along with Imperial College President Alice Gast).[211] In September 2018, Hancock led a "British business delegation talking healthtech in China":[212] "I'm in China this week to look at collaborating with our Chinese counterparts to harness the power of tech & innovation in healthcare."[213]

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[205] @chenweihua, Twitter, Apr. 3, 2020, https://twitter.com/chenweihua/status/1245987548717035520?s=20.

[206] Ministry of Foreign Affairs of the People's Republic of China, *Foreign Ministry Spokesperson Wang Wenbin's Regular Press Conference on September 18, 2020*, Sep. 18, 2020, https://www.fmprc.gov.cn/mfa_eng/xwfw_665399/s2510_665401/t1816244.shtml.

[207] Spencer Fernando, *Propaganda Patty Defends Communist China Yet Again*, Sept. 13, 2020, https://spencerfernando.com/2020/09/13/propaganda-patty-defends-communist-china-yet-again/.

[208] True North, *Hajdu slanders journalist as "dangerous" and "fake news"*, Nov. 26, 2020, https://tnc.news/2020/11/26/hajdu-slanders-journalist-as-dangerous-and-fake-news/.

[209] Denis Campbell, *Who's Matt Hancock? The health secretary's only legacy will be how quickly he's forgotten*, The Guardian, Jul. 24, 2019, https://www.theguardian.com/society/commentisfree/2019/jul/24/matt-hancock-health-secretary-legacy-quickly-forgotten-nhs.

[210] @MattHancock, Twitter, Jan. 19, 2018,https://twitter.com/MattHancock/status/954405324814979073?s=20.

[211] David Lee, *World Economic Forum Establishes "A.I. Council" Co-chaired by Chinese AI Expert Kai-Fu Lee*, Pandaily, Jan. 24, 2019, https://pandaily.com/world-economic-forum-establishes-artificial-intelligence-council/.

[212] @MattHancock, Twitter, Sep. 19, 2018, https://twitter.com/MattHancock/status/1042404125022072832?s=20.

[213] @MattHancock, Twitter, Sep. 17, 2018, https://twitter.com/MattHancock/status/1041692833994993665?s=20.

In April 2020, China's National Health Commission reported that Hancock and his Chinese counterpart, Ma Xioawei, had spoken over the phone to discuss future collaboration during the COVID-19 crisis: "Hancock spoke highly of China's commitment to fighting COVID-19 and China-UK cooperation during the pandemic, and said that the UK is willing to enhance exchanges and collaboration with China ..."[214] Three weeks later, CGTN reported that Hancock and Ma held a digital meeting of high-level health officials from China and the UK in a bid to increase cooperation amid the COVID-19 pandemic and beyond, including discussing "lockdown-lifting strategies:"

> Hancock said he appreciated the cooperation so far between the two nations in their joint response to the epidemic, and expressed that the UK is willing to strengthen anti-epidemic cooperation with China and to *use the epidemic prevention and control agreements as an opportunity to deepen bilateral health and global health cooperation...* They held in-depth discussions on topics including *lockdown-lifting strategies* and reiterated their willingness to strengthen experience sharing and technical cooperation to jointly safeguard the people of the two countries.[215] (emphasis added)

During the COVID-19 crisis, Christian Drosten assumed the role of Germany's most influential health official, though as a virologist he has little background in epidemiology, infectiology, or public health.[216] Drosten's central role in creating the wildly-inaccurate COVID-19 PCR test has already been discussed. In a May 14 press conference, Drosten referred to: "this concept in the pandemic research of 'The hammer and the dance,'" but this is not true—as discussed above, the term has no history, it was invented by Tomas Pueyo on March 19.

Daniel Andrews, Premier of Victoria, Australia, employs several advisors with ties to the CCP who have been involved in his strict pandemic policies. Danny Pearson, the MP who led Andrews' Belt and Road negotiations, lauded China's handling of the coronavirus.[217] Andrews' long-time staffer, Nancy Yang, attended a course in propaganda at a high-level CCP academy and helped spread COVID-19 disinformation early in the COVID-19 crisis.[218] Both Yang and

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[214] National Health Commission of the People's Republic of China, *NHC minister speaks on phone with UK health secretary*, Apr. 23, 2020, http://en.nhc.gov.cn/2020-04/23/c_79551.htm?bsh_bid=5572099213.

[215] CGTN, *Public health experts from China and UK move to develop greater cooperation*, May 16, 2020, https://newseu.cgtn.com/news/2020-05-16/Public-health-experts-from-China-and-UK-move-to-strengthen-ties-QwmBNLjJp6/share_amp.html?__twitter_impression=true.

[216] Tim Loh, *Germany Has Its Own Dr. Fauci—and Actually Follows His Advice*, Bloomberg Businessweek, Sept. 28, 2020, https://www.bloomberg.com/news/features/2020-09-28/christian-drosten-germany-s-dr-fauci-worries-about-second-wave-of-covid.

[217] Damon Johnston, *Daniel Andrews's BRI broker praises China on virus*, The Australian, Jun. 12, 2020, https://www.theaustralian.com.au/nation/politics/daniel-andrewss-bri-broker-praises-china-on-virus/news-story/eb8f6f79682e859331eb4393215ba31d.

[218] Rachel Baxendale, *Daniel Andrews staffer Nancy Yang did Chinese Communist propaganda course*, The Australian, Jun. 29, 2020, https://www.theaustralian.com.au/nation/politics/daniel-andrews-staffer-nancy-yang-did-chinese-communist-propaganda-course/news-story/eb49801365855bda4904c1a25a85650d; Alison Bevege, *Labor*

Andrews' senior advisor on China, Marty Mei, are members of the Chinese Community Council of Australia, the foremost United Front organization in Victoria.[219] Two senior figures in organizations linked to the Chinese Communist Party's foreign influence operation, Arthur Wu and Su Junxi, were chosen as COVID-19 "community ambassadors" in Andrews' government.[220]

Andrews previously signed onto Xi Jinping's Belt and Road initiative without consulting Prime Minister Scott Morrison, for which he was publicly rebuked.[221] Internal documents obtained under the freedom of information act show Andrews pitching for money and expertise from Chinese state-owned companies in his trip to China in October 2019, with a promise to "facilitate" their access to Victoria and "collaborate" on the state's biggest projects. Victoria, he said, would become "China's gateway to Australia."[222]

In August 2020, the city of Melbourne in Victoria became the first Australian city to implement Stage 4 lockdown—the strictest restrictions, with curfews and stiff fines.[223]

11. Prominent Lockdown Supporters Have Proven Unusually Indifferent to the Devastating Consequences of Their Policies

In addition to their pro-China bias, lockdown proponents have proven strangely stubborn in their support of these policies, continuing to promote economically- and socially-destructive measures seemingly without concern for their terrifying real-world consequences; tragically, these consequences are all too real.

Data from the website yelp.com has shown that over 60% of business closures during the COVID-19 crisis are now permanent, amounting to more than 97,000 businesses lost in the

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staffer with Chinese Communist Party links pushes bizarre conspiracy theory coronavirus was created by the U.S. and spread around the globe by its army, Daily Mail Australia, Jun. 1, 2020, https://www.dailymail.co.uk/news/article-8376701/Labor-staffer-Chinese-Communist-Party-links-pushes-bizarre-coronavirus-conspiracy-theory.html.

[219] Advance Australia, *How CCP Influence Runs Deep in Oz*, Jun. 12, 2020, https://www.advanceaustralia.org.au/how_ccp_influence_runs_deep_in_oz.

[220] Tom Minear, *'Community ambassadors' linked to Chinese Community Party*, Herald Sun, Dec. 1, 2020, https://www.heraldsun.com.au/news/victoria/community-ambassadors-linked-to-chinese-community-party/news-story/d5ce8fc1f27465f74a25e3ceaa3f4980.

[221] ABC News, *Prime Minister Scott Morrison, Victorian Premier Daniel Andrews clash over China deal*, Nov. 6, 2018, https://www.abc.net.au/news/2018-11-07/scott-morrison-daniel-andrews-clash-over-china-deal/10472026.

[222] Richard Baker, *'China's gateway': Daniel Andrews' Belt and Road pitch to Beijing*, The Age, Oct. 3, 2020, https://www.theage.com.au/politics/victoria/china-s-gateway-daniel-andrews-belt-and-road-pitch-to-beijing-20201002-p561b9.html.

[223] Kaeli Conforti, *Melbourne Begins Strict Stage 4 Lockdown This Week After Another Covid-19 Spike*, Forbes, Aug. 3, 2020, https://www.forbes.com/sites/kaeliconforti/2020/08/03/melbourne-begins-strict-level-4-lockdown-this-week-after-another-covid-19-spike/?sh=4ae9aa3150f9; Victoria Department of Health and Human Services, *Victoria's restriction levels*, https://web.archive.org/web/20200804100544/https://www.dhhs.vic.gov.au/victorias-restriction-levels-covid-19.

U.S.[224] Nearly half of black-owned small businesses have been wiped out.[225] Unemployment in the United States reached as high as 14.7% and highways jammed with thousands of vehicles awaiting their turn at food banks.[226] Nearly 5% of the population of the United Kingdom went hungry during the first three weeks of lockdown.[227]

A survey found that 22% of Canadians were experiencing high anxiety levels, a four-fold increase from before the COVID-19 crisis, while the number reporting symptoms of depression doubled to 13%.[228] More than 40 U.S. states have reported increases in opioid-related mortality.[229] And, according to the CDC, despite mass PCR testing and the enormous number of false positives, at least 100,947 excess deaths in 2020 were *not linked to COVID-19 at all.*[230]

Though at little risk from the virus itself, young people bore an outsized share of the burden of lockdown. More than seven in ten adults aged 18-23 said they experienced common symptoms of depression.[231] The CDC revealed that young adults aged 25-44 saw the largest increase in "excess" deaths from previous years, a stunning 26.5% jump,[232] despite accounting for *fewer than 3%* of deaths from COVID-19. This increase literally *surpassed* the increase in excess mortality of older Americans, who are at much higher risk of COVID-19 fatality. Since young people are at very low risk for COVID-19 fatality—20-49-year-olds have a 99.98% chance of surviving the virus, per CDC data—this shocking increase in deaths is largely attributable to deaths of "despair," in other words, deaths by lockdown.[233]

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[224] Anjali Sundaram, *Yelp data shows 60% of business closures due to the coronavirus pandemic are now permanent*, CNBC, Sep. 16 2020, https://www.cnbc.com/2020/09/16/yelp-data-shows-60percent-of-business-closures-due-to-the-coronavirus-pandemic-are-now-permanent.html.

[225] Pedro Nicolaci da Costa, *The Covid-19 Crisis Has Wiped Out Nearly Half Of Black Small Businesses*, Forbes, Aug. 10, 2020, https://www.forbes.com/sites/pedrodacosta/2020/08/10/the-covid-19-crisis-has-wiped-out-nearly-half-of-black-small-businesses/#2fc8c8334310.

[226] Jack Healy, *It's 'People, People, People' as Lines Stretch Across America*, N.Y. Times, Apr. 12, 2020, https://www.nytimes.com/2020/04/12/us/coronavirus-long-lines-america.html.

[227] Bethan Staton and Judith Evans, *Three million go hungry in UK because of lockdown*, Fin. Times, Apr. 10, 2020, https://www.ft.com/content/e5061be6-2978-4c0b-aa68-f372a2526826.

[228] Morganne Campbell, *Canadians reporting higher levels of anxiety, depression amid the pandemic*, Global News, Oct. 10, 2020, https://globalnews.ca/news/7391217/world-mental-health-day-canada/.

[229] American Medical Association, *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, Dec. 9, 2020, https://www.ama-assn.org/system/files/2020-12/issue-brief-increases-in-opioid-related-overdose.pdf.

[230] Lauren M. Rossen, PhD *et al.*, *Excess Deaths Associated with COVID-19, by Age and Race and Ethnicity — United States, January 26–October 3, 2020*, U.S. CDC MMWR Morb Mortal Wkly Rep Vol. 69(42), Oct. 23, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6942e2-H.pdf.

[231] Cory Stieg, *More than 7 in 10 Gen-Zers report symptoms of depression during pandemic, survey finds*, CNBC, Oct. 21 2020, https://www.cnbc.com/2020/10/21/survey-more-than-7-in-10-gen-zers-report-depression-during-pandemic.html.

[232] Amanda Prestigiacomo, *New CDC Numbers Show Lockdown's Deadly Toll On Young People*, The Daily Wire, Oct. 22, 2020, https://www.dailywire.com/news/new-cdc-numbers-show-lockdowns-deadly-toll-on-young-people.

[233] *Id.*

Suicides jumped to unprecedented levels around the world. "We've never seen numbers like this in such a short period of time," said Walnut Creek's Dr. Mike deBoisblanc. "I mean we've seen a year's worth of suicide attempts in the last four weeks."[234] "September of 2020 has been the highest month ever that we've seen suicidal patients admitted to our medical center," said Dr. Kia Carter, medical director of Psychiatry at Cook Children's Hospital.[235] In Japan, government statistics show suicide claimed more lives in October than Covid-19 has over the entire year to date.[236]

And, despite being at virtually no risk from COVID-19, as a result of lockdowns, children have suffered the most of all. Nearly one in four children living under COVID-19 lockdowns, social restrictions, and school closures are dealing with feelings of anxiety, with many at risk of lasting psychological distress.[237] In recent surveys of children and parents in the U.S., Germany, Finland, Spain and the U.K. by Save the Children, up to 65% of the children struggled with feelings of isolation.[238]

Children's health and intellectual development has regressed. Some who were potty-trained before lockdowns have reverted to diapers, and others have forgotten basic numbers or how to use a knife and fork.[239] According to the University of Wisconsin, during the COVID-19 crisis American children over the age of ten have engaged in 50% less physical activity.[240] Achievement gaps have widened, and early literacy progress has declined.[241] Per CDC, the proportion of mental health–related emergency visits for children aged 5–11 and 12–17 years increased approximately 24% and 31%, respectively.[242] And, most horrifying of all, a study found a 1493% rise in the incidence of abusive head trauma among children during the first month of lockdown in the U.K.[243]

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[240] The Economist, *Lockdowns could have long-term effects on children's health*, Jul. 19 2020, https://www.economist.com/international/2020/07/19/lockdowns-could-have-long-term-effects-on-childrens-health.

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These are not statistics. They're friends, neighbors, and citizens, whose lives have been needlessly destroyed by government policies. But while these statistics among the Nations may be horrifying, they pale in comparison to the suffering of untold millions in the developing world, cast into starvation and poverty as a result of our lockdowns. Autocracies grew more oppressive, and democracies took on autocratic characteristics.[244] In India, millions of stranded workers lost their livelihoods and marched in exodus to far-off villages.[245] In South Africa, food lines stretched for miles.[246] Quarantined migrants in Saudi Arabia were left to die. "The guards just throw the bodies out back as if it was trash."[247]

The United Nations forewarned of a "famine of biblical proportions" with 265 million people "literally marching to the brink of starvation,"[248] and later estimated that the crisis had "pushed an additional 150 million children into multidimensional poverty—deprived of education, health, housing, nutrition, sanitation or water."[249] All this for a virus that the WHO's peer-reviewed data[250] now reveals to have an infection fatality rate of 0.23%—0.05% in those under age 70—and which the WHO estimates might have already infected one in ten people worldwide by October.[251]

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[242] Rebecca T. Leeb, PhD *et al.*, *Mental Health–Related Emergency Department Visits Among Children Aged <18 Years During the COVID-19 Pandemic — United States, January 1–October 17, 2020*, U.S. CDC MMWR Morb Mortal Wkly Rep Vol. 69(45), Nov. 13, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/mm6945a3.htm.

[243] Jai Sidpra *et al.*, *Rise in the incidence of abusive head trauma during the COVID-19 pandemic*, Archives of Disease in Childhood, Jul. 2, 2020, http://dx.doi.org/10.1136/archdischild-2020-319872.

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According to the International Monetary Fund, the economy of just one G20 country grew during 2020: China.[252]

That lockdown supporters may not want to acknowledge these facts does not make them any less real. The suffering caused by these policies cannot be undone, but it can at least be prevented going forward, and justice can be obtained if these policies were imposed in bad faith.

Under the United Nations' Covenant on Civil and Political rights, it is incumbent on any government imposing disease control measures to utilize the "least restrictive means" available to effectively achieve the public health goal.[253] With the examples of Sweden, Florida, South Dakota, Belarus, and others successfully deploying means far less restrictive than China's lockdowns to manage COVID-19—without incurring any excess mortality or results worse than lockdown areas—it is difficult to understand how any world leader can continue to impose these measures in good faith.

CONCLUSION

In the 20th century, the term *totalitarian* was born to describe certain regimes that used modern technology to control every aspect of citizens' lives, binding them to the state by breaking all pre-existing social bonds. One such regime was the Soviet Union, and there is a growing expert consensus that China today is likewise totalitarian.[254] Totalitarian regimes utilize any and all means in the pathological monopolization of power. Though they deliver an exceptionally low quality of life to their citizens, totalitarian states are advanced political organisms, punching above their weight in geopolitics with their unparalleled ability to keep secrets and execute complex operations—the archetypal example being the clandestine rearmament of Germany in the 1930s. In the wilds of geopolitics, the lion underestimates the snake at its own peril, and with lockdowns, the CCP appears to have delivered the world a hefty dose of snake oil.

Both intelligence agencies and scientists may be forgiven for overlooking the CCP's lockdown fraud. The scientific concepts involved are complex enough to elude defense officials,[255] while the geopolitical implications of China's turn toward totalitarianism are certainly convoluted enough to have deceived scientists.

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Throughout 2020, lockdown measures have been quite popular, but that popularity is deceptive. For the general public, the idea that anyone might accept some outside incentive to support such devastating policies while knowing them to be ineffective—needlessly bankrupting millions of families and depriving millions of children of education and food—is, quite simply, too dark. Thus, the public supports lockdowns because the alternative—that they might have been implemented without good cause—is a possibility too evil for most to contemplate. But those who know history know that others with superficially excellent credentials have done even worse for even less.

Furthermore, most of the public believes that if there were anything untoward about the science behind lockdowns, intelligence agencies would stop them. For obvious reasons, those who work at intelligence agencies do not have the luxury of such complacency. Given the gravity of the decisions being made, we cannot ignore the possibility that the entire "science" of COVID-19 lockdowns has been a fraud of unprecedented proportion, deliberately promulgated by the Chinese Communist Party and its collaborators to impoverish the nations who implemented it.

This letter is to be construed only as a recommendation that the above matters be investigated by law-enforcement authorities as a matter of national security. This is not a formal criminal complaint, nor are these facts necessarily indicative that any crime may have been committed by any individual named herein, a determination that can be made only by appropriate legal authorities.

(Signatures appear on the following page)

Respectfully submitted this 10th day of January, 2021, by:

Michael P. Senger, Attorney
Stacey A. Rudin, Attorney
Dr. Clare Craig FRCPath, Consultant Diagnostic Pathologist
Robert Spalding, retired U.S. Air Force Brigadier General
Randy Hillier, MPP Lanark, Frontenac & Kingston
Francis Hoar, Barrister at Law
Sanjeev Sabhlok, PhD, former Commissioner in an Indian State Government
Brian O'Shea, Chief Operating Officer, Centurion Intelligence Partners
Maajid Nawaz, Activist, Author & Broadcaster
Simon Dolan, Business Leader & Entrepreneur

Swedish professor quits COVID-19 research amid hostility over his findings

By Yaron Steinbuch

March 2, 2021 | 7:57am | Updated

SWEDEN

A Swedish professor of epidemiology has quit researching COVID-19 after facing fierce backlash over his findings that the illness poses a low threat to children — undermining the political argument that schools can't reopen.

Jonas Ludvigsson, a professor of clinical epidemiology at the Karolinska Institute, said he has lost sleep as a result of the "angry messages through social media and email" assailing his study and partly blaming him for Sweden's contrarian COVID-19 strategy, the College Fix reported.

His research focused on children ages 1 to 16 during the first wave of the pandemic last spring, including those with "laboratory-verified or clinically verified COVID-19, including patients who were admitted for multisystem inflammatory syndrome in children" because it's "likely" related to the bug.The Karolinska Institute medical university in Stockholm, SwedenAlamy Stock Photo

Only 15 children went to the ICU — a rate of 0.77 per 100,000, according to the report. Four had "an underlying chronic coexisting condition" and none died.

As far as teachers, "fewer than" 30 ended up in the ICU during the same period — a rate of about 19 per 100,000.

Ludvigsson also noted that children weren't wearing face masks, while the rest of Swedish citizens were simply "encouraged" to practice social distancing.

Jonas Ludvigsson's research focused on children ages 1 to 16 during the first wave of the pandemic last spring.Karolinska Institute
Now, due to the backlash Ludvigsson faced over his research, Sweden plans to boost academic freedom protections in law, according to the College Fix.

Higher education minister Matilda Ernkrans told the British Medical Journal that the government is planning to amend the Higher Education Act to ensure "that education and research must be protected to enable people to freely discover, research and share knowledge."

Karolinska Institute president Ole Petter Ottersen told the journal that "hateful and scornful accusations and personal attacks cannot be tolerated," whether against the pediatrician or other researchers who have "retreat[ed] from the public debate after being threatened or harassed."

Ludvigsson said his letter to the editor, which was published in the Feb. 18 issue of the New England Journal of Medicine, had gone through several revisions and "formal external peer review," including statistically.

https://nypost.com/2021/03/02/professor-quits-covid-19-research-amid-hostility-over-his-findings/

NEWS

Masks 'don't work,' are damaging health and are being used to control population: Doctors panel

'There's no common sense to any of this. I am in control of my life. I'm going to do what my God given inalienable rights as an American and a human allow me to do'

Fri Feb 19, 2021 - 4:30 pm EST

THE NEW
SYMBOL OF
TYRANNY
MUZZLE

Scene from a May 2020 Pennsylvania anti-lockdown rallyMark Makela / Stringer/ Getty

By Michael Haynes

FOLLOW MICHAEL

Click HERE to register for access to replays of LifeSite's Unmasking COVID-19 conference.

February 19, 2021 (LifeSiteNews) – Masks "don't work," reveal a panel of doctors in LifeSiteNews' recent "Unmasking COVID-19," conference, who warned about how mask mandates are being used to bring about "Nazi-like" control of the populace.

As part of the LifeSiteNews unique event, Dr. Sheri Tenpenny, Dr. Eric Nepute and Dr. Pam Popper formed a panel discussion dealing with the issues of masks and vaccines, in which they highlighted the errors in the mainstream narrative, which promotes the wearing of masks almost everywhere.

Masks 'don't work'

"The only randomized control studies that have ever been done on masks show that they don't work," began Dr. Nepute. He referred to Dr. Anthony Fauci's "noble lie," in which Fauci "changed his tune," from his March 2020 comments, where he downplayed the need and efficacy of mask wearing, before urging Americans to use masks later in the year.

"Well, he lied to us. So if he lied about that, what else has he lied to you about?" questioned Nepute.

Masks have become commonplace in almost every setting, whether indoors or outdoors, but Dr. Popper mentioned how there have been "no studies" which actually examine the "effect of wearing a mask during all your waking hours."

"There's no science to back any of this and particularly no science to back the fact that wearing a mask twenty four-seven or every waking minute, is health promoting," added Popper.

"There's no data, there's no research that supports that wearing a mask is beneficial. In fact, if you look at the data that's been coming out, it's quite the contrary," stated Nepute.

— Article continues below Petition —

As mentioned by Nepute, a number of studies and demonstrations are now emerging, proving the inability of masks to prevent the passage of infection. In fact, Dr. Tenpenny commented how she had examined over one hundred peer reviewed articles, which all proved that "masks do nothing but make the wearer of the mask ill."

Masks actually undermining physical health

But more worrying than the failure of masks to perform their supposed purpose, the panel drew attention to the detrimental effects which masks can have on those who wear them. Referring to a recent study of 25,000 German students, Nepute mentioned that 68% of them had "some kind of impairment" from mask wearing.

Tenpenny weighed in, warning of the psychological effects which mask mandates will have on children. "We are training them to be fearful to breathe, that oxygen is horrible for them and that anybody that they see that doesn't wear a mask is dangerous to them," she said.

"And instead of thinking of people that had masks in the past where you would be afraid of the masked person, that they might be there to kidnap you or harm you or do something like that, instead, now we're seeing children who are like horrified that somebody doesn't have a mask on."

Aside from the mental effect of mask wearing, the panel also highlighted the danger which masks posed to the respiratory system. Nepute commented on the unusually large number of people having respiratory bacterial infections.

"If you look at what's happening right now and if you look at death certificates and you look at correlative deaths with COVID-19, what we find above all things is bacterial respiratory infections."

In a similar vein to her comments on COVID-19 experimental vaccines, Popper described those who are "consenting" to the mask mandates, as taking part in "a clinical trial without their permission that they are not even aware of."

Masks as a means of controlling the populace

As mask mandates have spread, so too, to some extent, has resistance. Such resistance has led to numerous instances of people without masks being confronted by other members of the public, shop employees and the police.

"This just reminds me of Nazi Germany, where, I mean, next they're going to put a star on my arm right," noted Popper. "And because where does it stop? It's a sign of submission, it has nothing to do with health."

People have been "brainwashed," into thinking "it's unsafe not to wear a mask," she continued. "They are turning the population against each other...this is a very common tactic that's been used by criminals and despots throughout history."

The "efficacy" of masks, which politicians point to, is in reality efficacy in bringing about "encephalopathy," Tenpenny said. "It will more effectively make their brains work less, which is what their goal is."

So effective has the campaign been in promoting fear and mask wearing, that Tenpenny predicted it could take "years" for people to stop wearing masks, even if the mandates stopped. "There would be a huge sector of the population that's going to keep wearing it for a long time because the fear based anxiety that has gotten embedded into their brain, they're not going to give it up."

Nor did she think it likely that globalist politicians would even release the mask mandates, suggesting the mandates would continue "as long as it's convenient for them [politicians] and as long as it propagates their agenda."

Tenpenny referred to the World Economic Forum's Great Reset agenda, and how it is crucially linked to the unprecedented restrictions being imposed upon the world. "It's all a planned mechanism way to dehumanize us, to separate us, to not touch each other and not shake hands, not do any of those things, to dehumanize us so that they can put us into an enslavement system of total control."

Presenting hope

However, the panel also urged people to have hope and courage. Nepute called for a "collective decision," where "millions of people" refused to comply, removed their masks and opened up their businesses again. Despite an initial period of "cognitive dissonance," Nepute expressed hope that many would soon reject the restrictions being imposed on them.

“There’s no common sense to any of this. I am in control of my life. I’m going to do what my God given inalienable rights as an American and a human allow me to do,” Nepute declared. “And I hope that more people realize that and stand up for that. Will we get some pushback? Yes. Who are we going to get pushback from? The very small amount of people that want to control everyone else.”

“I’m telling you, now is the time to take action,” he said.

Popper supported her colleague, presenting the example of many thousands of businesses in Italy which opened in defiance of lockdown laws: “at some point in time this will gather enough momentum where it will be unstoppable.”

“The people who are behind all of this, the people who are controlling us and this whole situation, they are godless, soulless creatures. They are brains inside of functioning bodies, but they have no soul. And people like this, if you look at history, they have never prevailed,” Popper reminded.

“They have never prevailed. They’re evil enough to use their brains to construct something like this and carry you off. But they never, ever win in the end. And so I think we can take our lessons from that and have a lot of hope for the future.”

Reference: https://www.lifesitenews.com/news/masks-dont-work-are-damaging-health-and-are-being-used-to-control-population-doctors-panel

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Facemasks in the COVID-19 era: A health hypothesis

Baruch Vainshelboim*

Cardiology Division, Veterans Affairs Palo Alto Health Care System/Stanford University, Palo Alto, CA, United States
*Address: VA Palo Alto Health Care System, Cardiology 111C, 3801 Miranda Ave, Palo Alto, CA 94304, United States.

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Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website. Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

Abstract

Many countries across the globe utilized medical and non-medical facemasks as non-pharmaceutical intervention for reducing the transmission and infectivity of coronavirus disease-2019 (COVID-19). Although, scientific evidence supporting facemasks' efficacy is lacking, adverse physiological, psychological and health effects are established. Is has been hypothesized that facemasks have compromised safety and efficacy profile and should be avoided from use. The current article comprehensively summarizes scientific evidences with respect to wearing facemasks in the COVID-19 era, providing prosper information for public health and decisions making.

Keywords: Physiology, Psychology, Health, SARS-CoV-2, Safety, Efficacy

Introduction

Facemasks are part of non-pharmaceutical interventions providing some breathing barrier to the mouth and nose that have been utilized for reducing the transmission of respiratory pathogens [1]. Facemasks can be medical and non-medical, where two types of the medical masks primarily used by healthcare workers [1], [2]. The first type is National Institute for Occupational Safety and Health (NIOSH)-certified N95 mask, a filtering face-piece respirator, and the second type is a surgical mask [1]. The designed and intended uses of N95 and surgical masks are different in the type of protection they potentially provide. The N95s are typically composed of electret filter media and seal tightly to the face of the wearer, whereas surgical masks are generally loose fitting and may or may not contain electret-filtering media. The N95s are designed to reduce the wearer's inhalation exposure to infectious and harmful particles from the environment such as during extermination of insects. In contrast, surgical masks are designed to provide a barrier protection against splash, spittle and other body fluids to spray from the wearer (such as surgeon) to the sterile environment (patient during operation) for reducing the risk of contamination [1].

The third type of facemasks are the non-medical cloth or fabric masks. The non-medical facemasks are made from a variety of woven and non-woven materials such as Polypropylene, Cotton, Polyester, Cellulose, Gauze and Silk. Although non-medical cloth or fabric facemasks are neither a medical device nor personal protective equipment, some standards have been developed by the French Standardization Association (AFNOR Group) to define a minimum performance for filtration and breathability capacity [2]. The current article reviews the scientific evidences with respect to safety and efficacy of wearing facemasks, describing the physiological and psychological effects and the potential long-term consequences on health.

Hypothesis

On January 30, 2020, the World Health Organization (WHO) announced a global public health emergency of severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) causing illness of coronavirus disease-2019 (COVID-19) [3]. As of October 1, 2020, worldwide 34,166,633 cases were reported and 1,018,876 have died with virus diagnosis. Interestingly, 99% of the detected cases with SARS-CoV-2 are asymptomatic or have mild condition, which contradicts with the virus name (*severe* acute respiratory syndrome-coronavirus-2) [4]. Although infection fatality rate (number of death cases divided by number of reported cases) initially seems quite high 0.029 (2.9%) [4], this overestimation related to limited number of COVID-19 tests performed which biases towards higher rates. Given the fact that asymptomatic or minimally symptomatic cases is several times higher than the number of reported cases, the case fatality rate is considerably less than 1% [5]. This was confirmed by the head of National Institute of Allergy and Infectious Diseases from US stating, "the overall clinical consequences of COVID-19 are similar to those of severe seasonal influenza" [5], having a case fatality rate of approximately 0.1% [5], [6], [7], [8]. In addition, data from hospitalized patients with COVID-19 and general public indicate that the majority of deaths were among older and chronically ill individuals, supporting the possibility that the virus may exacerbates existing conditions but rarely causes death by itself [9], [10]. SARS-CoV-2 primarily affects respiratory system and can cause complications such as acute respiratory distress syndrome (ARDS), respiratory failure and death [3], [9]. It is not clear however, what the scientific and clinical basis for wearing facemasks as protective strategy, given the fact that facemasks restrict breathing, causing hypoxemia and hypercapnia and increase the risk for respiratory complications, self-contamination and exacerbation of existing chronic conditions [2], [11], [12], [13], [14].

Of note, hyperoxia or oxygen supplementation (breathing air with high partial O_2 pressures that above the sea levels) has been well established as therapeutic and curative practice for variety acute and chronic conditions including respiratory complications [11], [15]. It fact, the current standard of care practice for treating hospitalized patients with COVID-19 is breathing 100% oxygen [16], [17], [18]. Although several countries mandated wearing facemask in health care settings and public areas, scientific evidences are lacking supporting their efficacy for reducing morbidity or mortality associated with infectious or viral diseases [2], [14], [19]. Therefore, it has been hypothesized: 1) the practice of wearing facemasks has compromised safety and efficacy profile, 2) Both medical and non-medical facemasks are ineffective to reduce human-to-human transmission and infectivity of SARS-CoV-2 and COVID-19, 3) Wearing facemasks has adverse physiological and psychological effects, 4) Long-term consequences of wearing facemasks on health are detrimental.

Evolution of hypothesis

Breathing Physiology

Breathing is one of the most important physiological functions to sustain life and health. Human body requires a continuous and adequate oxygen (O_2) supply to all organs and cells for normal function and survival. Breathing is also an essential process for removing metabolic byproducts [carbon dioxide (CO_2)] occurring during cell respiration [12], [13]. It is well established that acute significant deficit in O_2 (hypoxemia) and increased levels of CO_2 (hypercapnia) even for few minutes can be severely harmful and lethal, while chronic hypoxemia and hypercapnia cause health deterioration, exacerbation of existing conditions, morbidity and ultimately mortality [11], [20], [21], [22]. Emergency medicine demonstrates that 5–6 min of severe hypoxemia during cardiac arrest will cause brain death with extremely poor survival rates [20], [21], [22], [23]. On the other hand, chronic mild or moderate hypoxemia and hypercapnia such as from wearing facemasks resulting in shifting to higher contribution of anaerobic energy metabolism, decrease in pH levels and increase in cells and blood acidity, toxicity, oxidative stress, chronic inflammation, immunosuppression and health deterioration [24], [11], [12], [13].

Efficacy of facemasks

The physical properties of medical and non-medical facemasks suggest that facemasks are ineffective to block viral particles due to their difference in scales [16], [17], [25]. According to the current knowledge, the virus SARS-CoV-2 has a diameter of 60 nm to 140 nm [nanometers (billionth of a meter)] [16], [17], while medical and non-medical facemasks' thread diameter ranges from 55 µm to 440 µm [micrometers (one millionth of a meter), which is more than 1000 times larger [25]. Due to the difference in sizes between SARS-CoV-2 diameter and facemasks thread diameter (the virus is 1000 times smaller), SARS-CoV-2 can easily pass through any facemask [25]. In addition, the efficiency filtration rate of facemasks is poor, ranging from 0.7% in non-surgical, cotton-gauze woven mask to 26% in cotton sweeter material [2]. With respect to surgical and N95 medical facemasks, the efficiency filtration rate falls to 15% and 58%, respectively when even small gap between the mask and the face exists [25].

Clinical scientific evidence challenges further the efficacy of facemasks to block human-to-human transmission or infectivity. A randomized controlled trial (RCT) of 246 participants [123 (50%) symptomatic)] who were allocated to either wearing or not wearing surgical facemask, assessing viruses transmission including coronavirus [26]. The results of this study showed that among symptomatic individuals (those with fever, cough, sore throat, runny nose ect…) there was no difference between wearing and not wearing facemask for coronavirus droplets transmission of particles of >5 µm. Among asymptomatic individuals, there was no droplets or aerosols coronavirus detected from any participant with or without the mask, suggesting that asymptomatic individuals do not transmit or infect other people [26]. This was further supported by a study on infectivity where 445 asymptomatic individuals were exposed to asymptomatic SARS-CoV-2 carrier (been positive for

SARS-CoV-2) using close contact (shared quarantine space) for a median of 4 to 5 days. The study found that none of the 445 individuals was infected with SARS-CoV-2 confirmed by real-time reverse transcription polymerase [27].

A *meta*-analysis among health care workers found that compared to no masks, surgical mask and N95 respirators were not effective against transmission of viral infections or influenza-like illness based on six RCTs [28]. Using separate analysis of 23 observational studies, this *meta*-analysis found no protective effect of medical mask or N95 respirators against SARS virus [28]. A recent systematic review of 39 studies including 33,867 participants in community settings (self-report illness), found no difference between N95 respirators versus surgical masks and surgical mask versus no masks in the risk for developing influenza or influenza-like illness, suggesting their ineffectiveness of blocking viral transmissions in community settings [29].

Another *meta*-analysis of 44 non-RCT studies (n = 25,697 participants) examining the potential risk reduction of facemasks against SARS, middle east respiratory syndrome (MERS) and COVID-19 transmissions [30]. The *meta*-analysis included four specific studies on COVID-19 transmission (5,929 participants, primarily health-care workers used N95 masks). Although the overall findings showed reduced risk of virus transmission with facemasks, the analysis had severe limitations to draw conclusions. One of the four COVID-19 studies had zero infected cases in both arms, and was excluded from *meta*-analytic calculation. Other two COVID-19 studies had unadjusted models, and were also excluded from the overall analysis. The *meta*-analytic results were based on only one COVID-19, one MERS and 8 SARS studies, resulting in high selection bias of the studies and contamination of the results between different viruses. Based on four COVID-19 studies, the *meta*-analysis failed to demonstrate risk reduction of facemasks for COVID-19 transmission, where the authors reported that the results of *meta*-analysis have low certainty and are inconclusive [30].

In early publication the WHO stated that "facemasks are not required, as no evidence is available on its usefulness to protect non-sick persons" [14]. In the same publication, the WHO declared that "cloth (e.g. cotton or gauze) masks are not recommended under any circumstance" [14]. Conversely, in later publication the WHO stated that the usage of fabric-made facemasks (Polypropylene, Cotton, Polyester, Cellulose, Gauze and Silk) is a general community practice for "preventing the infected wearer transmitting the virus to others and/or to offer protection to the healthy wearer against infection (prevention)" [2]. The same publication further conflicted itself by stating that due to the lower filtration, breathability and overall performance of fabric facemasks, the usage of woven fabric mask such as cloth, and/or non-woven fabrics, should only be considered for infected persons and not for prevention practice in asymptomatic individuals [2]. The Central for Disease Control and Prevention (CDC) made similar recommendation, stating that only symptomatic persons should consider wearing facemask, while for asymptomatic individuals this practice is not recommended [31]. Consistent with the CDC, clinical scientists from Departments of Infectious Diseases and Microbiology in Australia counsel against facemasks usage for health-care workers, arguing that there is no justification for such practice while normal caring relationship between patients and medical staff could be compromised [32]. Moreover, the WHO repeatedly announced that "at present, there is no direct evidence (from studies on COVID-19) on the effectiveness face masking of healthy people in the community to prevent infection of respiratory viruses, including COVID-19"[2]. Despite these controversies, the potential harms and risks of wearing facemasks were clearly acknowledged. These including self-contamination due to hand practice or non-replaced when the mask is wet, soiled or damaged, development of facial skin lesions, irritant dermatitis or worsening acne and psychological discomfort.

Vulnerable populations such as people with mental health disorders, developmental disabilities, hearing problems, those living in hot and humid environments, children and patients with respiratory conditions are at significant health risk for complications and harm [2].

Physiological effects of wearing facemasks

Wearing facemask mechanically restricts breathing by increasing the resistance of air movement during both inhalation and exhalation process [12], [13]. Although, intermittent (several times a week) and repetitive (10–15 breaths for 2–4 sets) increase in respiration resistance may be adaptive for strengthening respiratory muscles [33], [34], prolonged and continues effect of wearing facemask is maladaptive and could be detrimental for health [11], [12], [13]. In normal conditions at the sea level, air contains 20.93% O_2 and 0.03% CO_2, providing partial pressures of 100 mmHg and 40 mmHg for these gases in the arterial blood, respectively. These gas concentrations significantly altered when breathing occurs through facemask. A trapped air remaining between the mouth, nose and the facemask is rebreathed repeatedly in and out of the body, containing low O_2 and high CO_2 concentrations, causing hypoxemia and hypercapnia [35], [36], [11], [12], [13]. Severe hypoxemia may also provoke cardiopulmonary and neurological complications and is considered an important clinical sign in cardiopulmonary medicine [37], [38], [39], [40], [41], [42]. Low oxygen content in the arterial blood can cause myocardial ischemia, serious arrhythmias, right or left ventricular dysfunction, dizziness, hypotension, syncope and pulmonary hypertension [43]. Chronic low-grade hypoxemia and hypercapnia as result of using facemask can cause exacerbation of existing cardiopulmonary, metabolic, vascular and neurological conditions [37], [38], [39], [40], [41], [42]. Table 1 summarizes the physiological, psychological effects of wearing facemask and their potential long-term consequences for health.

Table 1

Physiological and Psychological Effects of Wearing Facemask and Their Potential Health Consequences.

Physiological Effects	Psychological Effect	Health Consequences
• Hypoxemia • Hypercapnia • Shortness of breath • Increase lactate concentration • Decline in pH levels • Acidosis • Toxicity • Inflammation • Self-contamination • Increase in stress hormones level (adrenaline, noradrenaline and cortisol) • Increased muscle tension • Immunosuppression	• Activation of "fight or flight" stress response • Chronic stress condition • Fear • Mood disturbances • Insomnia • Fatigue • Compromised cognitive performance	• Increased predisposition for viral and infection illnesses • Headaches • Anxiety • Depression • Hypertension • Cardiovascular disease • Cancer • Diabetes • Alzheimer disease • Exacerbation of existing conditions and diseases • Accelerated aging process • Health deterioration • Premature mortality

In addition to hypoxia and hypercapnia, breathing through facemask residues bacterial and germs components on the inner and outside layer of the facemask. These toxic components are repeatedly rebreathed back into the body, causing self-contamination. Breathing through facemasks also increases temperature and humidity in the space between the mouth and the mask, resulting a release of toxic particles from the mask's materials [1], [2], [19], [26], [35], [36]. A systematic literature review estimated that aerosol contamination levels of facemasks including 13 to 202,549 different viruses [1]. Rebreathing contaminated air with high bacterial and toxic particle concentrations along with low O_2 and high CO_2 levels continuously challenge the body homeostasis, causing self-toxicity and immunosuppression [1], [2], [19], [26], [35], [36].

A study on 39 patients with renal disease found that wearing N95 facemask during hemodialysis significantly reduced arterial partial oxygen pressure (from PaO_2 101.7 to 92.7 mm Hg), increased respiratory rate (from 16.8 to 18.8 breaths/min), and increased the occurrence of chest discomfort and respiratory distress [35]. Respiratory Protection Standards from Occupational Safety and Health Administration, US Department of Labor states that breathing air with O_2 concentration below 19.5% is considered oxygen-deficiency, causing physiological and health adverse effects. These include increased breathing frequency, accelerated heartrate and cognitive impairments related to thinking and coordination [36]. A chronic state of mild hypoxia and hypercapnia has been shown as primarily mechanism for developing cognitive dysfunction based on animal studies and studies in patients with chronic obstructive pulmonary disease [44].

The adverse physiological effects were confirmed in a study of 53 surgeons where surgical facemask were used during a major operation. After 60 min of facemask wearing the oxygen saturation dropped by more than 1% and heart rate increased by approximately five beats/min [45]. Another study among 158 health-care workers using protective personal equipment primarily N95 facemasks reported that 81% (128 workers) developed new headaches during their work shifts as these become mandatory due to COVID-19 outbreak. For those who used the N95 facemask greater than 4 h per day, the likelihood for developing a headache during the work shift was approximately four times higher [Odds ratio = 3.91, 95% CI (1.35–11.31) p = 0.012], while 82.2% of the N95 wearers developed the headache already within ≤10 to 50 min [46].

With respect to cloth facemask, a RCT using four weeks follow up compared the effect of cloth facemask to medical masks and to no masks on the incidence of clinical respiratory illness, influenza-like illness and laboratory-confirmed respiratory virus infections among 1607 participants from 14 hospitals [19]. The results showed that there were no difference between wearing cloth masks, medical masks and no masks for incidence of clinical respiratory illness and laboratory-confirmed respiratory virus infections. However, a large harmful effect with more than 13 times higher risk [Relative Risk = 13.25 95% CI (1.74 to 100.97) was observed for influenza-like illness among those who were wearing cloth masks [19]. The study concluded that cloth masks have significant health and safety issues including moisture retention, reuse, poor filtration and increased risk for infection, providing recommendation against the use of cloth masks [19].

Psychological effects of wearing facemasks

Psychologically, wearing facemask fundamentally has negative effects on the wearer and the nearby person. Basic human-to-human connectivity through face expression is compromised and self-identity is somewhat eliminated [47], [48], [49]. These dehumanizing movements partially delete the uniqueness and individuality of person who wearing the facemask as well as the connected person [49]. Social connections and relationships are basic human needs, which innately inherited in all people, whereas reduced human-to-human connections are associated with poor mental and physical health [50], [51]. Despite escalation in technology and globalization that would presumably foster social connections, scientific findings show that people are becoming increasingly more socially isolated, and the prevalence of loneliness is increasing in last few decades [50], [52]. Poor social connections are closely related to isolation and loneliness, considered significant health related risk factors [50], [51], [52], [53].

A *meta*-analysis of 91 studies of about 400,000 people showed a 13% increased morality risk among people with low compare to high contact frequency [53]. Another *meta*-analysis of 148 prospective studies (308,849 participants) found that poor social relationships was associated with 50% increased mortality risk. People who were socially isolated or fell lonely had 45% and 40% increased mortality risk, respectively. These findings were consistent across ages, sex, initial health status, cause of death and follow-up periods [52]. Importantly, the increased risk for mortality was found comparable to smoking and exceeding well-established risk factors such as obesity and physical inactivity [52]. An umbrella review of 40 systematic reviews including 10 *meta*-analyses demonstrated that compromised social relationships were associated with increased risk of all-cause mortality, depression, anxiety suicide, cancer and overall physical illness [51].

As described earlier, wearing facemasks causing hypoxic and hypercapnic state that constantly challenges the normal homeostasis, and activates "fight or flight" stress response, an important survival mechanism in the human body [11], [12], [13]. The acute stress response includes activation of nervous, endocrine, cardiovascular, and the immune systems [47], [54], [55], [56]. These include activation of the limbic part of the brain, release stress hormones (adrenalin, neuro-adrenalin and cortisol), changes in blood flow distribution (vasodilation of peripheral blood vessels and vasoconstriction of visceral blood vessels) and activation of the immune system response (secretion of macrophages and natural killer cells) [47], [48]. Encountering people who wearing facemasks activates innate stress-fear emotion, which is fundamental to all humans in danger or life threating situations, such as death or unknown, unpredictable outcome. While acute stress response (seconds to minutes) is adaptive reaction to challenges and part of the survival mechanism, chronic and prolonged state of stress-fear is maladaptive and has detrimental effects on physical and mental health. The repeatedly or continuously activated stress-fear response causes the body to operate on survival mode, having sustain increase in blood pressure, pro-inflammatory state and immunosuppression [47], [48].

Long-Term health consequences of wearing facemasks

Long-term practice of wearing facemasks has strong potential for devastating health consequences. Prolonged hypoxic-hypercapnic state compromises normal physiological and psychological balance, deteriorating health and promotes the developing and progression of existing chronic diseases [23], [38], [39], [43], [47], [48], [57], [11], [12], [13]. For instance, ischemic heart disease caused by hypoxic damage to the myocardium is the most common form of cardiovascular disease and is a number one cause of death worldwide (44% of all non-communicable diseases) with 17.9 million deaths occurred in 2016 [57]. Hypoxia also playing an important role in cancer burden [58]. Cellular hypoxia has strong mechanistic feature in promoting cancer initiation, progression, metastasis, predicting clinical outcomes and usually presents a poorer survival in patients with cancer. Most solid tumors present some degree of hypoxia, which is independent predictor of more aggressive disease, resistance to cancer therapies and poorer clinical outcomes [59], [60]. Worth note, cancer is one of the leading causes of death worldwide, with an estimate of more than 18 million new diagnosed cases and 9.6 million cancer-related deaths occurred in 2018 [61].

With respect to mental health, global estimates showing that COVID-19 will cause a catastrophe due to collateral psychological damage such as quarantine, lockdowns, unemployment, economic collapse, social isolation, violence and suicides [62], [63], [64]. Chronic stress along with hypoxic and hypercapnic conditions knocks the body out of balance, and can cause headaches, fatigue, stomach issues, muscle tension, mood disturbances, insomnia and accelerated aging [47], [48], [65], [66], [67]. This state suppressing the immune system to protect the body from viruses and bacteria, decreasing cognitive function, promoting the developing and exacerbating the major health issues including hypertension, cardiovascular disease, diabetes, cancer, Alzheimer disease, rising anxiety and depression states, causes social isolation and loneliness and increasing the risk for prematurely mortality [47], [48], [51], [56], [66].

Conclusion

The existing scientific evidences challenge the safety and efficacy of wearing facemask as preventive intervention for COVID-19. The data suggest that both medical and non-medical facemasks are ineffective to block human-to-human transmission of viral and infectious disease such SARS-CoV-2 and COVID-19, supporting against the usage of facemasks. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response,

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rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression. Long-term consequences of wearing facemask can cause health deterioration, developing and progression of chronic diseases and premature death. Governments, policy makers and health organizations should utilize prosper and scientific evidence-based approach with respect to wearing facemasks, when the latter is considered as preventive intervention for public health.

CRediT authorship contribution statement

Baruch Vainshelboim: Conceptualization, Data curation, Writing - original draft.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Original ResearchMarch 2021

Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers

FREE

A Randomized Controlled Trial

Henning Bundgaard, DMSc

,

Johan Skov Bundgaard, BSc

, … View all authors

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SUPPLEMENTAL MATERIAL

VISUAL ABSTRACT
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Abstract

Background:

Observational evidence suggests that mask wearing mitigates transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is uncertain if this observed association arises through protection of uninfected wearers (protective effect), via reduced transmission from infected mask wearers (source control), or both.

Objective:

To assess whether recommending surgical mask use outside the home reduces wearers' risk for SARS-CoV-2 infection in a setting where masks were uncommon and not among recommended public health measures

Design:

Randomized controlled trial (DANMASK-19 [Danish Study to Assess Face Masks for the Protection Against COVID-19 Infection]). (ClinicalTrials.gov: NCT04337541)

Setting:

Denmark, April and May 2020.

Participants:

Adults spending more than 3 hours per day outside the home without occupational mask use.

Intervention:

Encouragement to follow social distancing measures for coronavirus disease 2019, plus either no mask recommendation or a recommendation to wear a mask when outside the home among other persons together with a supply of 50 surgical masks and instructions for proper use.

Measurements:

The primary outcome was SARS-CoV-2 infection in the mask wearer at 1 month by antibody testing, polymerase chain reaction (PCR), or hospital diagnosis. The secondary outcome was PCR positivity for other respiratory viruses.

Results:

A total of 3030 participants were randomly assigned to the recommendation to wear masks, and 2994 were assigned to control; 4862 completed the study. Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was −0.3 percentage point (95% CI, −1.2 to 0.4 percentage point; $P = 0.38$) (odds ratio, 0.82 [CI, 0.54 to 1.23]; $P = 0.33$). Multiple imputation accounting for loss to follow-up yielded similar results. Although the difference observed

was not statistically significant, the 95% CIs are compatible with a 46% reduction to a 23% increase in infection.

Limitation:

Inconclusive results, missing data, variable adherence, patient-reported findings on home tests, no blinding, and no assessment of whether masks could decrease disease transmission from mask wearers to others.

Conclusion:

The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use. The data were compatible with lesser degrees of self-protection.

Primary Funding Source:

The Salling Foundations.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the cause of coronavirus disease 2019 (COVID-19), has infected more than 54 million persons (1, 2). Measures to impede transmission in health care and community settings are essential (3). The virus is transmitted person-to-person, primarily through the mouth, nose, or eyes via respiratory droplets, aerosols, or fomites (4, 5). It can survive on surfaces for up to 72 hours (6), and touching a contaminated surface followed by face touching is another possible route of transmission (7). Face masks are a plausible means to reduce transmission of respiratory viruses by minimizing the risk that respiratory droplets will reach wearers' nasal or oral mucosa. Face masks are also hypothesized to reduce face touching (8, 9), but frequent face and mask touching has been reported among health care personnel (10). Observational evidence supports the efficacy of face masks in health care settings (11, 12) and as source control in patients infected with SARS-CoV-2 or other coronaviruses (13).

An increasing number of localities recommend masks in community settings on the basis of this observational evidence, but recommendations vary and controversy exists (14). The World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (15) strongly recommend that persons with symptoms or known infection wear masks to prevent transmission of SARS-CoV-2 to others (source control) (16). However, WHO acknowledges that we lack evidence that wearing a mask protects healthy persons from SARS-CoV-2 (prevention) (17). A systematic review of observational studies reported that mask use reduced risk for SARS, Middle East respiratory syndrome, and COVID-19 by 66% overall, 70% in health care workers, and 44% in the community (12). However, surgical and cloth masks were grouped in preventive studies, and none of the 3 included non–health care studies related directly to COVID-19. Another systematic review (18) and American College of Physicians recommendations (19) concluded that evidence on mask effectiveness for respiratory infection prevention is stronger in health care than community settings.

Observational evidence suggests that mask wearing mitigates SARS-CoV-2 transmission, but whether this observed association arises because masks protect uninfected wearers (protective effect) or because transmission is reduced from infected mask wearers (source control) is uncertain. Here, we report a randomized controlled trial (20) that assessed whether a recommendation to wear a surgical mask when outside the home among others reduced wearers' risk for SARS-CoV-2 infection in a setting where public health measures were in effect but community mask wearing was uncommon and not recommended.

Methods

Trial Design and Oversight

DANMASK-19 (Danish Study to Assess Face Masks for the Protection Against COVID-19 Infection) was an investigator-initiated, nationwide, unblinded, randomized controlled trial (ClinicalTrials.gov: NCT04337541). The trial protocol was registered with the Danish Data Protection Agency (P-2020-311) (Part 10 of the Supplement) and published (21). The researchers presented the protocol to the independent regional scientific ethics committee of the Capital Region of Denmark, which did not require ethics approval (H-20023709) in accordance with Danish legislation (Parts 11 and 12 of the Supplement). The trial was done in accordance with the principles of the Declaration of Helsinki.

Participants and Study Period

During the study period (3 April to 2 June 2020), Danish authorities did not recommend use of masks in the community and mask use was uncommon (<5%) outside hospitals (22). Recommended public health measures included quarantining persons with SARS-CoV-2 infection, social distancing (including in shops and public transportation, which remained open), limiting the number of persons seen, frequent hand hygiene and cleaning, and limiting visitors to hospitals and nursing homes (23, 24). Cafés and restaurants were closed during the study until 18 May 2020.

Eligible persons were community-dwelling adults aged 18 years or older without current or prior symptoms or diagnosis of COVID-19 who reported being outside the home among others for at least 3 hours per day and who did not wear masks during their daily work. Recruitment involved media advertisements and contacting private companies and public organizations. Interested citizens had internet access to detailed study information and to research staff for questions (Part 3 of the Supplement). At baseline, participants completed a demographic survey and provided consent for researchers to access their national registry data (Parts 4 and 5 of the Supplement). Recruitment occurred from 3 through 24 April 2020. Half of participants were randomly assigned to a group on 12 April and half on 24 April.

Intervention

Participants were enrolled and data registered using Research Electronic Data Capture (REDCap) software (25). Eligible participants were randomly assigned 1:1 to the mask or control group using a computer algorithm and were stratified by the 5 regions of Denmark (Supplement Table 1). Participants were notified of allocation by email, and study packages were sent by courier (Part 7 of the Supplement). Participants in the mask group were instructed to wear a mask when outside the home during the next month. They received 50 three-layer, disposable, surgical face masks with ear loops (TYPE II EN 14683 [Abena]; filtration rate, 98%; made in China). Participants in both groups received materials and instructions for antibody testing on receipt and at 1 month. They also received materials and instructions for collecting an oropharyngeal/nasal swab sample for polymerase chain reaction (PCR) testing at 1 month and whenever symptoms compatible with COVID-19 occurred during follow-up. If symptomatic, participants were strongly encouraged to seek medical care. They registered symptoms and results of the antibody test in the online REDCap system. Participants returned the test material by prepaid express courier.

Written instructions and instructional videos guided antibody testing, oropharyngeal/nasal swabbing, and proper use of masks (Part 8 of the Supplement), and a help line was available to participants. In accordance with WHO recommendations for health care settings at that time, participants were instructed to change the mask if outside the home for more than 8 hours. At baseline and in weekly follow-up e-mails, participants in both groups were encouraged to follow current COVID-19 recommendations from the Danish authorities.

Antibody and Viral PCR Testing

Participants tested for SARS-CoV-2 IgM and IgG antibodies in whole blood using a point-of-care test (Lateral Flow test [Zhuhai Livzon Diagnostics]) according to the manufacturer's recommendations and as previously described (26). After puncturing a fingertip with a lancet, they withdrew blood into a capillary tube and placed 1 drop of blood followed by 2 drops of saline in the test chamber in each of the 2 test plates (IgM and IgG). Participants reported IgM and IgG results separately as “1 line present” (negative), “2 lines present” (positive), or “I am not sure, or I could not perform the test” (treated as a negative result). Participants were categorized as seropositive if they had developed IgM, IgG, or both. The manufacturer reported that sensitivity was 90.2% and specificity 99.2%. A previously reported internal validation using 651 samples from blood donors before

November 2019 and 155 patients with PCR-confirmed SARS-CoV-2 infection estimated a sensitivity of 82.5% (95% CI, 75.3% to 88.4%) and specificity of 99.5% (CI, 98.7% to 99.9%) (26). We (27) and others (28) have reported that oropharyngeal/nasal swab sampling for SARS-CoV-2 by participants, as opposed to health care workers, is clinically useful. Descriptions of RNA extraction, primer and probe used, reverse transcription, preamplification, and microfluidic quantitative PCR are detailed in Part 6 of the Supplement.

Data Collection

Participants received 4 follow-up surveys (Parts 4 and 5 of the Supplement) by e-mail to collect information on antibody test results, adherence to recommendations on time spent outside the home among others, development of symptoms, COVID-19 diagnosis based on PCR testing done in public hospitals, and known COVID-19 exposures.

Outcomes

The primary outcome was SARS-CoV-2 infection, defined as a positive result on an oropharyngeal/nasal swab test for SARS-CoV-2, development of a positive SARS-CoV-2 antibody test result (IgM or IgG) during the study period, or a hospital-based diagnosis of SARS-CoV-2 infection or COVID-19. Secondary end points included PCR evidence of infection with other respiratory viruses (Supplement Table 2).

Sample Size Calculations

The sample size was determined to provide adequate power for assessment of the combined composite primary outcome in the intention-to-treat analysis. Authorities estimated an incidence of SARS-CoV-2 infection of at least 2% during the study period. Assuming that wearing a face mask halves risk for infection, we estimated that a sample of 4636 participants would provide the trial with 80% power at a significance level of 5% (2-sided α level). Anticipating 20% loss to follow-up in this community-based study, we aimed to assign at least 6000 participants.

Statistical Analysis

Participants with a positive result on an antibody test at baseline were excluded from the analyses. We calculated CIs of proportions assuming binomial distribution (Clopper–Pearson).

The primary composite outcome (intention-to-treat) was compared between groups using the χ^2 test. Odds ratios and confidence limits were calculated using logistic regression. We did a per protocol analysis that included only participants reporting complete or predominant use of face masks as instructed. A conservative sensitivity analysis assumed that participants with a positive result on an antibody test at the end of the study who had not provided antibody test results at study entrance had had a positive result at entrance. To further examine the uncertainty of loss to follow-up, we did (post hoc) 200 imputations using the R package smcfcs, version 1.4.1 (29), to impute missing values of outcome. We included sex, age, type of work, time out of home, and outcome in this calculation.

Prespecified subgroups were compared by logistic regression analysis. In a post hoc analysis, we explored whether there was a subgroup defined by a constellation of participant characteristics for which a recommendation to wear masks seemed to be effective. We included sex, age, type of work, time out of home, and outcome in this calculation.

Two-sided *P* values less than 0.05 were considered statistically significant. Analyses were done using R, version 3.6.1 (R Foundation).

Role of the Funding Source

An unrestricted grant from the Salling Foundations supported the study, and the BESTSELLER Foundation donated the Livzon tests. The funders did not influence study design, conduct, or reporting.

Results

Participants

A total of 17 258 Danish citizens responded to recruitment, and 6024 completed the baseline survey and fulfilled eligibility criteria. The first participants (group 1; *n* = 2995) were randomly assigned on 12 April 2020 and were followed from 14 to 16 April through 15 May 2020. Remaining participants (group 2; *n* = 3029) were randomly assigned on 24 April 2020 and were followed from 2 to 4 May through 2 June 2020. A total of 3030 participants were randomly assigned to the recommendation to wear face masks, and 2994 were assigned not to wear face masks (Figure); 4862 participants (80.7%) completed the study. Table 1 shows baseline characteristics, which were well balanced between groups. Participants reported having spent a median of 4.5 hours per day outside the home.

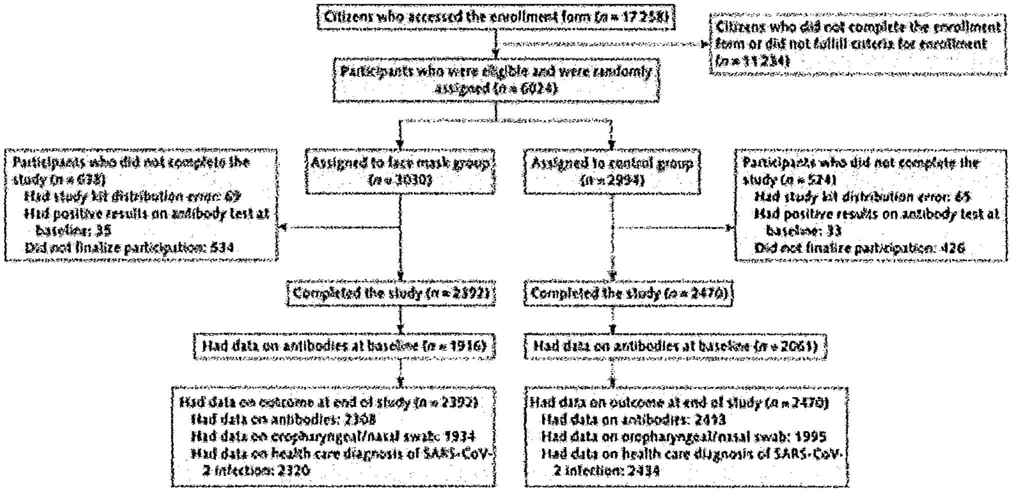
Citizens who accessed the enrollment form (n = 17 258)
Citizens who did not complete the enrollment form or did not fulfill criteria for enrollment (n = 11 234)
Participants who were eligible and were randomly assigned (n = 6024)
Participants who did not complete the study (n = 638)
Had study kit distribution error: 69
Had positive results on antibody test at baseline: 35
Did not finalize participation: 534
Assigned to face mask group (n = 3030)
Assigned to control group (n = 2994)
Participants who did not complete the study (n = 524)
Had study kit distribution error: 65
Had positive results on antibody test at baseline: 33
Did not finalize participation: 426
Completed the study (n = 2392)
Completed the study (n = 2470)
Had data on antibodies at baseline (n = 1916)
Had data on antibodies at baseline (n = 2061)
Had data on outcome at end of study (n = 2392)
Had data on antibodies: 2308
Had data on oropharyngeal/nasal swab: 1934
Had data on health care diagnosis of SARS-CoV-2 infection: 2320
Had data on outcome at end of study (n = 2470)
Had data on antibodies: 2413
Had data on oropharyngeal/nasal swab: 1995
Had data on health care diagnosis of SARS-CoV-2 infection: 2434

Figure. Study flow diagram.

Inclusion and exclusion criteria are described in the Methods section, and criteria for completion of the study are given in the Supplement. SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

- Download figure
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Table 1. Characteristics of Participants Completing the Study

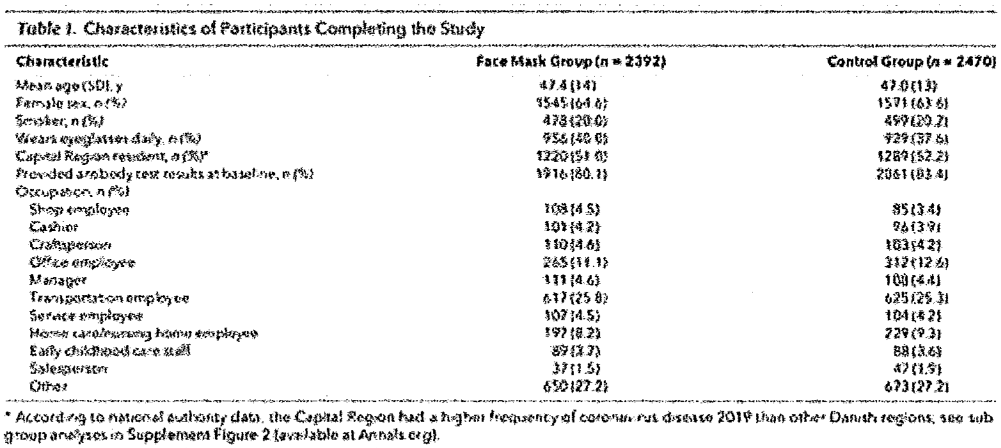

Table 1. Characteristics of Participants Completing the Study

Characteristic	Face Mask Group (*n* = 2392)	Control Group (*n* = 2470)
Mean age (SD), y	47.4 (14)	47.0 (13)
Female sex, *n* (%)	1545 (64.6)	1571 (63.6)
Smoker, *n* (%)	478 (20.0)	499 (20.2)
Wears eyeglasses daily, *n* (%)	956 (40.0)	929 (37.6)
Capital Region resident, *n* (%)*	1220 (51.0)	1289 (52.2)
Provided antibody test results at baseline, *n* (%)	1916 (80.1)	2061 (83.4)
Occupation, *n* (%)		
Shop employee	108 (4.5)	85 (3.4)
Cashier	101 (4.2)	96 (3.9)
Craftsperson	110 (4.6)	103 (4.2)
Office employee	265 (11.1)	312 (12.6)
Manager	111 (4.6)	108 (4.4)
Transportation employee	617 (25.8)	625 (25.3)
Service employee	107 (4.5)	104 (4.2)
Home care/nursing home employee	197 (8.2)	229 (9.3)
Early childhood care staff	89 (3.7)	88 (3.6)
Salesperson	37 (1.5)	47 (1.9)
Other	650 (27.2)	673 (27.2)

* According to national authority data, the Capital Region had a higher frequency of coronavirus disease 2019 than other Danish regions; see subgroup analyses in Supplement Figure 2 (available at Annals.org).

Adherence

Based on the lowest adherence reported in the mask group during follow-up, 46% of participants wore the mask as recommended, 47% predominantly as recommended, and 7% not as recommended.

Primary Outcome

The primary outcome occurred in 42 participants (1.8%) in the mask group and 53 (2.1%) in the control group. In an intention-to-treat analysis, the between-group difference was −0.3 percentage point (CI, −1.2 to 0.4 percentage point; $P = 0.38$) (odds ratio [OR], 0.82 [CI, 0.54 to 1.23]; $P = 0.33$) in favor of the mask group (Supplement Figure 1). When this analysis was repeated with multiple imputation for missing data due to loss to follow-up, it yielded similar results (OR, 0.81 [CI, 0.53 to 1.23]; $P = 0.32$). Table 2 provides data on the components of the primary end point, which were similar between groups.

Table 2. Distribution of the Components of the Composite Primary Outcome

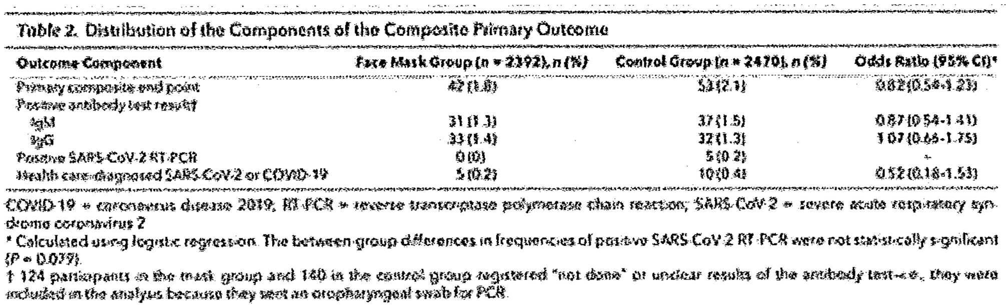

Table 2. Distribution of the Components of the Composite Primary Outcome

Outcome Component	Face Mask Group (n = 2392), n (%)	Control Group (n = 2470), n (%)	Odds Ratio (95% CI)*
Primary composite end point	42 (1.8)	53 (2.1)	0.82 (0.54–1.23)
Positive antibody test result†			
IgM	31 (1.3)	37 (1.5)	0.87 (0.54–1.41)
IgG	33 (1.4)	32 (1.3)	1.07 (0.66–1.75)
Positive SARS-CoV-2 RT-PCR	0 (0)	5 (0.2)	–
Health care–diagnosed SARS-CoV-2 or COVID-19	5 (0.2)	10 (0.4)	0.52 (0.18–1.53)

COVID-19 = coronavirus disease 2019; RT-PCR = reverse transcriptase polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2

* Calculated using logistic regression. The between-group differences in frequencies of positive SARS-CoV-2 RT-PCR were not statistically significant (P = 0.079).

† 124 participants in the mask group and 140 in the control group registered "not done" or unclear results of the antibody test—i.e., they were included in the analysis because they sent an oropharyngeal swab for PCR.

In a per protocol analysis that excluded participants in the mask group who reported nonadherence (7%), SARS-CoV-2 infection occurred in 40 participants (1.8%) in the mask group and 53 (2.1%) in the control group (between-group difference, −0.4 percentage point [CI, −1.2 to 0.5 percentage point]; *P* = 0.40) (OR, 0.84 [CI, 0.55 to 1.26]; *P* = 0.40). Supplement Figure 2 provides results of the prespecified subgroup analyses of the primary composite end point. No statistically significant interactions were identified.

In the preplanned sensitivity analysis, those who had a positive result on an antibody test at 1 month but had not provided antibody results at baseline were considered to have had positive results at baseline (*n* = 18)—that is, they were excluded from the analysis. In this analysis, the primary outcome occurred in 33 participants (1.4%) in the face mask group and 44 (1.8%) in the control group (between-group difference, −0.4 percentage point [CI, −1.1 to 0.4 percentage point]; *P* = 0.22) (OR, 0.77 [CI, 0.49 to 1.22]; *P* = 0.26).

Three post hoc (not preplanned) analyses were done. In the first, which included only participants reporting wearing face masks "exactly as instructed," infection (the primary outcome) occurred in 22 participants (2.0%) in the face mask group and 53 (2.1%) in the control group (between-group difference, −0.2 percentage point [CI, −1.3 to 0.9 percentage point]; *P* = 0.82) (OR, 0.93 [CI, 0.56 to 1.54]; *P* = 0.78). The second post hoc analysis excluded participants who did not provide antibody test results at baseline; infection occurred in 33 participants (1.7%) in the face mask group and 44 (2.1%) in the control group (between-group difference, −0.4 percentage point [CI, −1.4 to 0.4 percentage point]; *P* = 0.33) (OR, 0.80 [CI, 0.51 to 1.27]; *P* = 0.35). In the third post hoc analysis, which investigated constellations of patient characteristics, we did not find a subgroup where face masks were effective at conventional levels of statistical significance (data not shown).

A total of 52 participants in the mask group and 39 control participants reported COVID-19 in their household. Of these, 2 participants in the face mask group and 1 in the control group developed SARS-CoV-2 infection, suggesting that the source of most observed infections was outside the home. Reported symptoms did not differ between groups during the study period (Supplement Table 3).

Secondary Outcomes

In the mask group, 9 participants (0.5%) were positive for 1 or more of the 11 respiratory viruses other than SARS-CoV-2, compared with 11 participants (0.6%) in the control group (between-group difference, −0.1 percentage point [CI, −0.6 to 0.4 percentage point]; $P = 0.87$) (OR, 0.84 [CI, 0.35 to 2.04]; $P = 0.71$). Positivity for any virus, including SARS-CoV-2, occurred in 9 mask participants (0.5%) versus 16 control participants (0.8%) (between-group difference, −0.3 percentage point [CI, −0.9 to 0.2 percentage point]; $P = 0.26$) (OR, 0.58 [CI, 0.25 to 1.31]; $P = 0.19$).

Discussion

In this community-based, randomized controlled trial conducted in a setting where mask wearing was uncommon and was not among other recommended public health measures related to COVID-19, a recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, incident SARS-CoV-2 infection compared with no mask recommendation. We designed the study to detect a reduction in infection rate from 2% to 1%. Although no statistically significant difference in SARS-CoV-2 incidence was observed, the 95% CIs are compatible with a possible 46% reduction to 23% increase in infection among mask wearers. These findings do offer evidence about the degree of protection mask wearers can anticipate in a setting where others are not wearing masks and where other public health measures, including social distancing, are in effect. The findings, however, should not be used to conclude that a recommendation for everyone to wear masks in the community would not be effective in reducing SARS-CoV-2 infections, because the trial did not test the role of masks in source control of SARS-CoV-2 infection. During the study period, authorities did not recommend face mask use outside hospital settings and mask use was rare in community settings (22). This means that study participants' exposure was overwhelmingly to persons not wearing masks.

The observed infection rate was similar to that reported in other large Danish studies during the study period (26, 30). Of note, the observed incidence of SARS-CoV-2 infection was higher than we had estimated when planning a sample size that would ensure more than 80% power to detect a 50% decrease in infection. The intervention lasted only 1 month and was carried out during a period when Danish authorities recommended quarantine of diagnosed patients, physical distancing, and hand hygiene as general protective means against SARS-CoV-2 transmission (23). Cafés and restaurants were closed through 18 May, but follow-up of the second randomized group continued through 2 June.

The first randomized group was followed while the Danish society was under lockdown. Reopening occurred (18 May 2020) during follow-up of the second group of participants, but it was not reflected in the outcome because infection rates were similar between groups (Supplement Figure 2). The relative infection rate between mask wearers and those not wearing masks would most likely be affected by changes in applied protective means or in the virulence of SARS-CoV-2, whereas the rate difference between the 2 groups would probably not be affected solely by a higher—or lower—number of infected citizens.

Although we saw no statistically significant difference in presence of other respiratory viruses, the study was not sufficiently powered to draw definite conclusions about the protective effect of masks for other viral infections. Likewise, the study had limited power for any of the subgroup analyses.

The primary outcome was mainly defined by antibodies against SARS-CoV-2. This definition was chosen because the viral load of infected patients may be only transiently detectable (31, 32) and because approximately half of persons infected with SARS-CoV-2 are asymptomatic (26, 33). Masks have been hypothesized to reduce inoculum size (34) and could increase the likelihood that infected mask users are asymptomatic, but this hypothesis has been challenged (35). For these reasons, we did not rely solely on identification of SARS-CoV-2 in oropharyngeal/nasal swab samples. As mentioned in the Methods section, an internal validation study estimated that the point-of-care test has 82.5% sensitivity and 99.5% specificity (26).

The observed rate of incident SARS-CoV-2 infection was similar to what was estimated during trial design. These rates were based on thorough screening of all participants using antibody measurements combined with PCR, whereas the observed official infection rates relied solely on PCR test–based estimates during the period. In addition, authorities tested only a small subset of primarily symptomatic citizens of the entire population, yielding low incidence rates. On this basis, the infection rates we report here are not comparable with the official SARS-CoV-2 infection rates in the Danish population. The eligibility requirement of at least 3 hours of exposure to other persons outside the home would add to this difference. Between 6 April and 9 May 2020, we found a similar seroprevalence of SARS-CoV-2 of 1.9% (CI, 0.8% to 2.3%) in Danish blood donors using the Livzon point-of-care test and assessed by laboratory technicians (36). Testing at the end of follow-up, however, may not have captured any infections contracted during the last part of the study period, but this would have been true in both the mask and control groups and was not expected to influence the overall findings.

The face masks provided to participants were high-quality surgical masks with a filtration rate of 98% (37). A published meta-analysis found no statistically significant difference in preventing influenza in health care workers between respirators (N95 [American standard] or FFP2 [European standard]) and surgical face masks (38). Adherence to mask use may be higher than observed in this study in settings where mask use is common. Some mask group participants (14%) reported adverse reactions from other citizens (Supplement Table 4).

Although adherence may influence the protective effect of masks, sensitivity analyses had similar results across reported adherence.

How SARS-CoV-2 is transmitted—via respiratory droplets, aerosols, or (to a lesser extent) fomites—is not firmly established. Droplets are larger and rapidly fall to the ground, whereas aerosols are smaller (≤5 μm) and may evaporate and remain in the air for hours (39). Transmission of SARS-CoV-2 may take place through multiple routes. It has been argued that for the primary route of SARS-CoV-2 spread—that is, via droplets—face masks would be considered effective, whereas masks would not be effective against spread via aerosols, which might penetrate or circumnavigate a face mask (37, 39). Thus, spread of SARS-CoV-2 via aerosols would at least partially explain the present findings. Lack of eye protection may also have been of importance, and use of face shields also covering the eyes (rather than face masks only) has been advocated to halt the conjunctival route of transmission (40, 41). We observed no statistically significant interaction between wearers and nonwearers of eyeglasses (Supplement Figure 2). Recent reports indicate that transmission of SARS-CoV-2 via fomites is unusual (42), but masks may alter behavior and potentially affect fomite transmission.

The present findings are compatible with the findings of a review of randomized controlled trials of the efficacy of face masks for prevention (as personal protective equipment) against influenza virus (18). A recent meta-analysis that suggested a protective effect of face masks in the non–health care setting was based on 3 observational studies that included a total of 725 participants and focused on transmission of SARS-CoV-1 rather than SARS-CoV-2 (12). Of 725 participants, 138 (19%) were infected, so the transmission rate seems to be higher than for SARS-CoV-2. Further, these studies focused on prevention of infection in healthy mask wearers from patients with a known, diagnosed infection rather than prevention of transmission from persons in their surroundings in general. In addition, identified comparators (control participants) not wearing masks may also have missed other protective means. Recent observational studies that indicate a protective association between mandated mask use in the community and SARS-CoV-2 transmission are limited by study design and simultaneous introduction of other public health interventions (14, 43).

Several challenges regarding wearing disposable face masks in the community exist. These include practical aspects, such as potential incorrect wearing, reduced adherence, reduced durability of the mask depending on type of mask and occupation, and weather. Such circumstances may necessitate the use of multiple face masks during the day. In our study, participants used a mean of 1.7 masks per weekday and 1.3 per weekend day (Supplement Table 4). Wearing a face mask may be physically unpleasant, and psychological barriers and other side effects have been described (44). "Face mask policing" between citizens might reinforce use of masks but may be challenging. In addition, the wearer of a face mask may change to a less cautious behavior because of a false sense of security, as pointed out by WHO (17); accordingly, our face mask group seemed less worried (Supplement Table 4), which may explain their increased willingness to wear face masks in the future (Supplement Table 5). These challenges, including costs and availability, may reduce the efficacy of face masks to prevent SARS-CoV-2 infection.

The potential benefits of a community-wide recommendation to wear masks include combined prevention and source control for symptomatic and asymptomatic persons, improved attention, and reduced potential stigmatization of persons wearing masks to prevent infection of others (17). Although masks may also have served as source control in SARS-CoV-2–infected participants, the study was not designed to determine the effectiveness of source control.

The most important limitation is that the findings are inconclusive, with CIs compatible with a 46% decrease to a 23% increase in infection. Other limitations include the following. Participants may have been more cautious and focused on hygiene than the general population; however, the observed infection rate was similar to findings of other studies in Denmark (26, 30). Loss to follow-up was 19%, but results of multiple imputation accounting for missing data were similar to the main results. In addition, we relied on patient-reported findings on home antibody tests, and blinding to the intervention was not possible. Finally, a randomized controlled trial provides high-level evidence for treatment effects but can be prone to reduced external validity.

Our results suggest that the recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, the incidence of SARS-CoV-2 infection in mask wearers in a setting where social distancing and other public health measures were in effect, mask recommendations were not among those measures, and community use of masks was uncommon. Yet, the findings were inconclusive and cannot definitively exclude a 46% reduction to a 23% increase in infection of mask wearers in such a setting. It is important to emphasize that this trial did not address the effects of masks as source control or as protection in settings where social distancing and other public health measures are not in effect.

Reduction in release of virus from infected persons into the environment may be the mechanism for mitigation of transmission in communities where mask use is common or mandated, as noted in observational studies. Thus, these findings do not provide data on the effectiveness of widespread mask wearing in the community in reducing SARS-CoV-2 infections. They do, however, offer evidence about the degree of protection mask wearers can anticipate in a setting where others are not wearing masks and where other public health measures, including social distancing, are in effect. The findings also suggest that persons should not abandon other COVID-19 safety measures regardless of the use of masks. While we await additional data to inform mask recommendations, communities must balance the seriousness of COVID-19, uncertainty about the degree of source control and protective effect, and the absence of data suggesting serious adverse effects of masks (45).

Reference: https://www.acpjournals.org/doi/full/10.7326/M20-6817

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Corona children studies "Co-Ki": First results of a Germany-wide registry on mouth and nose covering (mask) in children

Silke Schwarz
University of Witten/Herdecke
Ekkehart Jenetzky
University of Witten/Herdecke
Hanno Krafft
University of Witten/Herdecke https://orcid.org/0000-0002-8199-8874
Tobias Maurer
University of Witten/Herdecke
David Martin (✉ David.Martin@uni-wh.de)
University of Witten/Herdecke

Research Article

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Abstract

Background: Narratives about complaints in children and adolescents caused by wearing a mask are accumulating. There is, to date, no registry for side effects of masks.

Methods: At the University of Witten/Herdecke an online registry has been set up where parents, doctors, pedagogues and others can enter their observations. On 20.10.2020, 363 doctors were asked to make entries and to make parents and teachers aware of the registry.

Results: By 26.10.2020 the registry had been used by 20,353 people. In this publication we report the results from the parents, who entered data on a total of 25,930 children. The average wearing time of the mask was 270 minutes per day. Impairments caused by wearing the mask were reported by 68% of the parents. These included irritability (60%), headache (53%), difficulty concentrating (50%), less happiness (49%), reluctance to go to school/kindergarten (44%), malaise (42%) impaired learning (38%) and drowsiness or fatigue (37%).

Discussion: This world's first registry for recording the effects of wearing masks in children is dedicated to a new research question. The frequency of the registry's use and the spectrum of symptoms registryed indicate the importance of the topic and call for representative surveys, randomized controlled trials with various masks and a renewed risk-benefit assessment for the vulnerable group of children: adults need to collecticely reflect the circumstances under which they would be willing to take a residual risk upon themselves in favor of enabling children to have a higher quality of life without having to wear a mask.

Background And Questions

The question of a certificate of exemption from the obligation to wear a mouth and nose cover (hereinafter referred to as "mask") is a new phenomenon in pediatric practice. Parents, educators and doctors are increasingly reporting problems and health complaints in children in connection with wearing a mask. There are no manufacturer-independent studies on the use of masks for children and adolescents that are certified as medical products for occupational safety in professional applications. In addition, due to the unknown materials used, there are no findings on the potential protective effects or side effects of the often home-made "everyday masks" worn by the majority of children. In view of the ongoing measures to contain the COVID-19 pandemic, and in particular the varying obligations for children and adolescents to wear masks in school over a longer period of time, there is an urgent need for research.

Study Design And Research Methods

Based on the registry of adverse drug reactions at the Paul Ehrlich Institute (www.nebenwirkungen.pei.de), an online registry has been set up where parents, doctors, educators and others can enter their observations on the effects of wearing a mask on children and adolescents. On 20.10.2020, 363 doctors on the Co-Ki study distribution list were informed about the possibility of making entries there themselves and to communicate the registry to their patients and colleagues. The registry and the questionnaire can be found online at www.co-ki-masken.de (Figure in Online Supplement S1) as part of the Co-Ki study complex (figure in Online Supplement S2). The data entered in the registry includes information regarding the role of the registrant, demographic data, previous illnesses, situation and duration of mask wearing, type of mask, existence of complaints from the child about an impairment via the mask, symptoms, behavioral problems, personal attitude to corona protection measures of the government and the possibility to leave name and e-mail address. A positive ethics vote from the University of Witten/Herdecke was obtained.

Results

By the evening of 26.10.2020, one week after the registry went online, 20,353 people had already taken part in the survey, with 48,657 entries. Of the survey participants, 17,854 (87.7%) were parents, 736 (3.6%) were teachers, 352 (1.7%) were doctors, and 1,411 (6.9%) were "others" (Figure S3 in the Online Supplement shows the analysis set of the entries of the first week). This article reports on the 17,854 entering parents with a total of 25,930 children and youth. The data of the entering doctors, teachers and other roles are published separately.

Of the 17,854 entering parents, 6,877 (38.5%) stated that they had a university degree (bachelor, master, master's degree, diploma, state examination, doctorate), 671 (3.8%) had a master craftsman, 3,704 (20.7%) had completed an apprenticeship and 3,040 (17.0%) had a high school diploma (general qualification for university entrance) or subject-related higher education entrance qualification or technical college entrance qualification. 2,509 (14.1%) of the participants stated that their highest educational level was a secondary school leaving certificate (In Germany: *Mittlere Reife, Fachoberschulereife* or similar), 327 participants (1.8%) had a secondary modern school leaving certificate, and 31 participants (0.2%) stated that they had no school or training qualification. The remaining did not enter an education. The participation of contributors per state corresponds to the distribution of the population (Figure 1).

The demographic situation of the children and previous illnesses among the children from the parents' point of view are shown in Table 1: the genders are equally represented with a slight trend towards boys; and 55.6% of the children were between 7-12 years of age. In 79.4% of the children it was stated that they had no previous illnesses, 5.9% had asthma and 1.8% had another lung disease. Furthermore, there was the possibility of free text entries on other previous illnesses, which was used by 8.6%.

Table 1: *Demography and pre-existing conditions of children*

		Total age group	Age group 0-6 years	Age group 7-12 years	Age group 13-18 years	Test for difference
	Age group n (%)	25 926* (100%)	4 002 (15.4%)	14 407 (55.6%)	7 517 (29.0%)	
Gender	Male	12 589 (48.5%)	1 880 (47.0%)	7 027 (48.8%)	3 682 (49.0%)	p = 0.0002
	Female	12 248 (47.2%)	1 899 (47.5%)	6 790 (47.1%)	3 559 (47.3%)	
	Divers	62 (0.2%)	13 (0.3%)	32 (0.2%)	17 (0.2%)	
	Without specification	1 031* (4.0%)	210 (5.2%)	558 (3.9%)	259 (3.4%)	
Pre-existing conditions	No previous illnesses	20 586 (79.4%)	3 400 (85.0%)	11 606 (80.6%)	5 580 (74.2%)	p < 0.0001
	Asthma	1 541 (5.9%)	123 (3.1%)	801 (5.6%)	617 (8.2%)	
	Other lung diseases	458 (1.8%)	50 (1.2%)	251 (1.7%)	157 (2.1%)	
	Other previous illnesses (free text input)	2 232 (8.6%)	233 (5.8%)	1 178 (8.2%)	821 (10.9%)	
	Not specified	1 110 (4.3%)	196 (4.9%)	571 (4.0%)	343 (4.5%)	

* for four children the age specification is missing.

Table 2 presents the situation of wearing masks with the children and whether any form of impairment from parents view was present. When asked about the situations in which the children wear a mask, 81.1% of the survey participants answered that the child wears the mask at school outside of class, i.e. during breaks and in the corridors, 48.6% also stated that the child also wears the mask in class at the seat during lessons. 68.5% of the children recorded wearing the mask in stores and 39% on the way to school 4.6% of the children never wear a mask.A mask exemption certificate had been granted to 6.7% of the registered children and youth. The average length of time the mask was worn varies greatly with age; it averaged 4.5 hours per day, and was much higher, especially among youth (13-18 years), averaging 6 hours (Table 2). In 16 913 children (65.2%) it was reported that fabric masks were worn, followed by surgical masks. FPP masks are hardly worn by children.

Regarding the question as to whether children themselves complain about impairments caused by wearing the mask, 67.7% of the respondents answered yes for their children; 26% answered no. The question as to whether the respondents themselves observed an impairment of the child by wearing the mask was answered yes in 66.1% (Table 2). The assessment of the health impairment is shown in Table 3. Four percent had no opinion when asked about their personal attitude to the government's corona protection measures, 11.7% of the participants thought that the measures should be more stringent, 11.0% considered the current measures appropriate and good and 41.7% were in favor of milder measures. A further 31.6% expressed a different opinion than the setting option specified in the selection option. In general, they described the policy measures as inappropriate, incomprehensible and undifferentiated.

Table 2: *Wearing situation of the mask and impairment*

	Wearing situation (Total Age group)		**Wearing situation (Total Age group)**	**Wearing situation (Total Age group)**	**Wearing situation (Total Age group)**	**Wearing situation (Total Age group)**	**Wearing situation (Total Age group)**
	Wearing time in minutes (IQR)**		270 (120;390)	90 (30;240)	240 (120;370)	360 (240; 450)	p < 0.0001
Type of Mask	Fabric mask		16 913 (65.2%)	2 501 (62,5%)	10 311 (71,6%)	4 101 (54,6%)	p < 0.0001
	Surgical Mask		5 542 (21.4%)	271 (6,8%)	2 619 (18,2%)	2 652 (35,3%)	
	FFP mask		536 (2.1%)	51 (1,3%)	273 (1,9%)	212 (2,8%)	
	Not specified		2 935 (11.3%)	1 179 (29.5%)	1 204 (8.4%)	552 (7.3%)	
Impairments	Impairment by mask according to child	Yes	17 550 (67.7%)	1 607 (40.2%)	10 244 (71.1%)	5 699 (75.8%)	p < 0.0001
		No	6 801 (26.2%)	1 431 (35.8%)	3 744 (26.0%)	1 626 (21.6%)	p < 0.0001
		Not specified	1.575 (6.1%)	964 (24.1%)	419 (2.9%)	192 (2.6%)	p < 0.0001
	Have you observed any adverse effects of a mask on your child?	Yes	17.125 (66.1%)	1.640 (41.0%)	9.980 (69.3%)	5.505 (73.2%)	p < 0.0001
		No	6.841 (26.4%)	1.367 (34,2%)	3.810 (26.4%)	1.664 (22.1%)	p < 0.0001
		Not specified	1.960 (7.6%)	995 (24.9%)	617 (4.3%)	348 (4.6%)	p < 0.0001
The child must wear a mask...	on the way to school		10.105 (39.0%)	668 (16.7%)	5.704 (39.6%)	3.733 (49.7%)	p < 0.0001
	in school outside the classroom (corridor, playground)		20.124 (81.1%)	1.834 (45.8%)	12.682 (88.0%)	5.608 (86.6%)	p < 0.0001
	at school in class		12 593 (48.6%)	713 (17.8%)	6 880 (47.8%)	5 000 (66.5%)	p < 0.0001
	in kindergarten		361 (1.4%)	295 (7.4%)	53 (0.4%)	13 (0.2%)	p < 0.0001
	in stores		17 763 (68.5%)	2 060 (51.5%)	10 237 (71.1%)	5 466 (72.7%)	p < 0.0001
	never		1.198 (4.6%)	933 (24.8%)	155 (1.1%)	50 (0.7%)	p < 0.0001
	has a certificate of mask release		1.732 (6.7%)	144 (3.6%)	1.045 (7.3%)	543 (7.2%)	p < 0.0001
	** IQR (interquartile range) n = 4427 (17.1%) missing.						

The frequency distribution of the above-mentioned side effects associated with masks is similar in the different age groups, with headaches, concentration difficulties, discomfort, learning difficulties and drowsiness / tiredness being the most common (Table 3). Other complaints were described in the free text. First of all: 269 entries on worsened skin, especially increased pimples, rashes and allergic phenomena around the mouth area up to fungal diseases in and around the mouth. There were 151 entries on nosebleeds, 122 entries on school displeasure up to school anxiety / refusal to attend school, 64 entries on increased sweating, 52 entries on pressure points and wounds behind the ears, 46 entries on sore or cracked and partly bloody lips, 31 entries on increased migraine attacks in frequency and severity, 23 entries on impaired vision, 13 entries on aphthae. Table 3 shows the classification of a possible health impairment of the children, as assessed by the parents. Table 4 shows further behavioral problems in the children, above all with 60.4% an increased irritability, 49.3% less happy children, 44% children who do not want to go to school anymore, in each case children in the age category 7-12 years are affected most. In 25.3% of the children it was stated that they have developed new anxieties (Table 4). In addition, 2,672 entries in this question alone mention explicit specifications of anxiety or the reappearance of several anxieties in free text entries. In addition to a general fear of the future, the fear of suffocation even with a mask, as well as the fear of death of relatives through corona, is most frequently represented. In addition, there is the fear of stigmatization both by wearing and not wearing a mask in the social environment. Many parents also report nightmares and anxiety disorders that relate to masked people whose facial expressions and identity are not recognizable to the children. A detailed evaluation and publication of the free text entries is planned.

Table 3: *Symptoms in children in parental report*

	Total age group	**Age group 0-6 years**	**Age group 7-12 years**	**Age group 13-18 years**	**Test for difference**
Headaches	13.811 (53.3%)	960 (24.0%)	7.863 (54.6%)	4.988 (66.4%)	p < 0.0001
Concentration difficulties	12.824 (49.5%)	961 (24.0%)	7.313 (50.8%)	4.550 (60.5%)	p < 0.0001
Discomfort	10.907 (42.1%)	1.040 (26.0%)	6.369 (44.2%)	3.498 (46.5%)	p < 0.0001
Impairment in learning	9.845 (38.0%)	621 (15.5%)	5.604 (38.9%)	3.620 (48.2%)	p < 0.0001
drowsiness / tiredness	9.460 (36.5%)	729 (18.2%)	5.163 (35.8%)	3.568 (47.5%)	p < 0.0001
Tightness under the mask	9.232 (35.6%)	968 (24.2%)	5.427 (37.7%)	2.837 (37.7%)	p < 0.0001
Feeling of shortness of breath	7.700 (29.7%)	677 (16.9%)	4.440 (30.8%)	2.583 (34.4%)	p < 0.0001
Dizziness	6.848 (26.4%)	427 (10.7%)	3.814 (26.5%)	2.607 (34.7%)	p < 0.0001
Dry neck	5.883 (22.7%)	516 (12.9%)	3.313 (23.0%)	2.054 (27.3%)	p < 0.0001
Syncope	5.365 (20.7%)	410 (10.2%)	2.881 (20.0%)	2.074 (27.6%)	p < 0.0001
Unwillingness to move, unwillingness to play	4.629 (17.9%)	456 (11.4%)	2.824 (19.6%)	1.349 (17.9%)	p < 0.0001
Itching in the nose	4.431 (17.1%)	513 (12.8%)	2550 (17.7%)	1.368 (18.2%)	p < 0.0001
Nausea	4.292 (16.6%)	310 (7.7%)	2.544 (17.7%)	1.438 (19.1%)	p < 0.0001
Feeling of weakness	3.820 (14.7%)	300 (7.5%)	2.020 (14.0%)	1.500 (20.0%)	p < 0.0001
Abdominal pain	3.492 (13.5%)	397 (9.9%)	2.292 (15.9%)	803 (10.7%)	p < 0.0001
Accelerated respiration	3.170 (12.2%)	417 (10.4%)	1.796 (12.5%)	957 (12.7%)	p < 0.0001
Disease feeling	2.503 (9.7%)	205 (5.1%)	1.328 (9.2%)	970 (12.9%)	p < 0.0001
Tightness in the chest	2.074 (8.0%)	161 (4.0%)	1.122 (7.8%)	791 (10.5%)	p < 0.0001
Flickering eyes	2.027 (7.8%)	149 (3.7%)	1.047 (7.3%)	831 (11.1%)	p < 0.0001
Loss of appetite	1.812 (%)	182 (4.5%)	1.099 (7.6%)	531 (7.1%)	p < 0.0001
tachycardia, stumbling heart stings	1.459 (5.6%)	118 (2.9%)	766 (5.3%)	575 (7.6%)	p < 0.0001
Noise in the ears	1.170	107	632	440	p < 0.0001

	(4.5%)	(2.7%)	(4.4%)	(5.9%)	
Short-term impairment of consciousness / fainting spells	565 (2.2%)	39 (1.0%)	274 (1.9%)	252 (3.4%)	p < 0.0001
Vomiting	480 (1.9%)	40 (1.0%)	296 (2.1%)	144 (1.9%)	p < 0.0001

Table 4: *Further behavior of the children, changed by wearing the mask, from parents' point of view*

	Total age group	**Age group 0-6 years**	**Age group 7-12 years**	**Age group 13-18 years**	**Test for difference**
The child is more often irritated than usual	11 364 (60.4%)	1 041 (40.0%)	6 566 (62.1%)	3 757 (66.5%)	p < 0.0001
The child is less cheerful	9 286 (49.3%)	959 (36.9%)	5 640 (53.3%)	2 687 (47.6%)	p < 0.0001
The child no longer wants to go to school/kindergarten	8 280 (44.0%)	824 (31.7%)	5 168 (48.9%)	2 288 (40.5%)	p < 0.0001
The child is more restless than usual	5 494 (29.2%)	773 (29.7%)	3 515 (33.2%)	1 206 (21.4%)	p < 0.0001
The child sleeps worse than usual	5 849 (31.1%)	633 (24.3%)	3 507 (33.2%)	1 709 (30.3%)	p < 0.0001
No other abnormalities	7 103 (27.4%)	1 400 (35.0%)	3 834 (26.6%)	1 869 (24.9%)	p < 0.0001
The child has developed new fears	4 762 (25.3%)	713 (27.4%)	2 935 (27.8%)	1 114 (19.7%)	p < 0.0001
The child sleeps more than usual	4 710 (25.0%)	319 (12.3%)	2 183 (20.6%)	2 208 (39.1%)	p < 0.0001
The child plays less	2 912 (15.5%)	400 (15.4%)	1.998 (18.9%)	514 (9.1%)	p < 0.0001
The child has a greater urge to move than usual	1 615 (8.6%)	253 (9.7%)	1.124 (10.6%)	238 (4.2%)	p < 0.0001

The optional possibility to leave name and e-mail address for possible questions was used by 27.1% (5 513) of the participants. A validation performed with the software *Bouncer* proved 4 710 (85.4%) of the mail addresses to be reachable.

Discussion

The explosiveness of the topic and the need for communication of the interviewees are made clear by the "viral" use of the registry within a few days after publication, leading within one week to 25 930 parental entries for affected children in Germany (approx. 0.2% of the population). The fact that 23.1% of the participating parents used the optional possibility of leaving their name and valid e-mail address for possible questions shows the seriousness of the entries. According to the status report of the Robert Koch Institute (RKI) of October 25, 2020, there were a total of 429 181 reported infections in Germany, with an increasing trend, of which 8 764 (3.6% of the reported) were under 10 years of age and 16 548 (6.7% of the reported) were between 10 and 19 years of age [1]. This is less than the number of children reported in this registry within one week. It is still unclear whether children are less likely than adults to be infected with SARS-CoV-2 and transmit the infection to adults in such a way that the latter become seriously ill [2-5]. However, it has been shown that the majority of infected children, especially up to the age of 10, develop no or only mild symptoms [6-9]. In rare cases, children up to the age of 10 years develop severe courses of the disease. The one child and two adolescents who have died of COVID-19 (as of 25.10.2020, not yet described in detail by the RKI) had chronic pre-existing conditions [10, 11]. In Europe, children under 10 years of age rarely seem to be spreaders in this infection process, although data from India, a country with a different hygiene background, do ascribe a certain transmission role to children (although without differentiation between 5-year-olds and 17-year-olds) [12]. A Scottish study of 300 000 households found that the more children in the household, the less likely adults are to be hospitalized with COVID-19 [13]. A recent study suggests that children emit less aerosol when singing and talking than adults [14].

Based on our data, it can be said that the effects of compulsory masks on the quality of life and presumably also on the health of individual children should not be ignored by politics and society. While many children tolerate the mask relatively easily, there are clearly children who cannot be expected to wear a mask in good conscience, especially when the effectiveness of the mouth and nose protection in smaller children is questionable. Parents, teachers and doctors report stigmatization, exclusion and aggressive behavior towards children who do not wear a mask for psychological or medical reasons. Inappropriate use of masks, which tends to be the case in children, may increase the risk of pathogen spread and transmission through the increased tendency to put their fingers in their face, and may thus be worse than not wearing a mask at all in some cases [15]. Looking at the symptom spectrum of the complaints, 66.1% of the interviewees show a clear and broadly diversified burden of complaints, both in the physical (rashes, headaches, etc.), as well as in the mental (fears, irritability, etc.) and intellectual (concentration disorders) areas in the children of the interviewees. In addition to acute health impairments with, in individual cases, significantly experienced health impairments, the long-term effects on the various developmental areas that go beyond well-being, such as language, play, learning, communication, sensomotoric development and empathy of children are difficult to assess. The often mentioned headaches and concentration difficulties should be seriously explored in their importance for cognitive development. It is noticeable that the distribution of complaints fits well with the age of the children (Tables 3 and 4), which supports the plausibility of parental input.

Direct effects of indoor CO2 concentration on cognitive functions have been demonstrated [16]. This is not directly transferable to the air breathed under the masks, but increased CO2 concentrations could occur under some mask types. This may be particularly true in small children with large fabric masks, which sometimes have a thicker material and which were used particularly frequently by the children in the registry (65.2%). Families are currently free to choose their children's mask type according to the thickness of the material and thus there is still a margin between breathable and multi-layer, rather airtight models, yet the problem remains that parents, regardless of whether or not they themselves approve of the corona protection measures, can overburden their children through ignorance or fear of infection by using masks that are inappropriate for their child. A benefit-risk analysis is therefore called for. However, this is complicated by the fact that the study situation is extremely weak both in terms of benefits and risks. Both the calculations of a benefit from masks and almost all studies of the risks of masks are based on adults. It must also be assumed that the SARS-CoV-2 protection standards for schools, such as those of the German statutory accident insurance, are not known everywhere [17]. In particular, they contain recommendations on recovery times when wearing masks for schoolchildren with short breaks and, at the latest after three hours of wearing, a subsequent recovery time of 15-30 minutes [17].

Limitation of the results: Even though the rapid development of the registry and the high number of participants within a few days is impressive, this first evaluation of the Co-Ki mask registry has limitations. The fact that 38.5% of the participants indicated a university degree could be an indication that the registry was not equally accessible to all groups of people as an online version and due to its complexity. All online registries have this problem. A reporting bias (also with regard to the preferential documentation of particularly severely affected children) cannot be ruled out. In addition, the link to the registry was also found in social media forums, among other places, which criticize the government's corona protection measures in principle, which is partly reflected in the results of the query on attitudes to the government's corona protection measures. At the same time, other participants reported that their children had no complaints.

Both the gender distribution and the distribution of participants according to federal states, as well as the distribution of symptoms according to age, speak in favor of the data being representative for the German population of children. With a few exceptions, the data sets in the free text entries reflect differentiated, sincere parents and, taken as a whole, provide a balanced overall picture with a plausible spectrum of symptoms and a comprehensive description of the impairments observed in children in connection with the mask. The hundreds of incoming e-mails to the study initiators, including questions about the existence of the registry, specification and completion of the entries made by participants, detailed case descriptions and suggestions for further research, are a further indication of the high relevance of the topic and the honesty with which many participants address the question. Naturally, an openly accessible registry can never provide a medical counter-validation of all submissions. The number of entries in the registry is continuing to increase daily. The registry questionnaire will be expanded and validated on the basis of the new symptoms entered by parents in the free text information.

Conclusion

Many children are subject to great challenges and families try to master these as best they can. While the proportion of people tested positive for SARS-CoV-2 and also the number of intensive care patients in

Germany is high in many places, we report here on a relatively small, unrepresentative problem: several thousand children who seem to suffer from wearing the mask or who may experience health problems from the mask. Our study provides the basis for a representative survey on which a precise benefit-risk analysis of mask wearing in children can be built.

" Conclusion For The Practice"

- A certain percentage of children and adolescents have non-negligible complaints when wearing the mask. These children should not be stigmatized.

- This worldwide first registry on side effects of the mask reflects the spectrum of symptoms in children and adolescents.

- A precise benefit-risk analysis is urgently required. The occurrence of reported side effects in children due to wearing the masks must be taken seriously and requires a precise clarification of the accompanying health circumstances, the situation of wearing the mask (duration, breaks and mask type) and the school situation.

- Furthermore, all parents, doctors, pedagogues and others are invited to participate in www.co-ki-masken.de to document their observations on effects that occur when wearing the mask. The registry will also be available in English from 15.12.2020.

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Supplemental Information

Supplemental Information is not available with this version

Figures

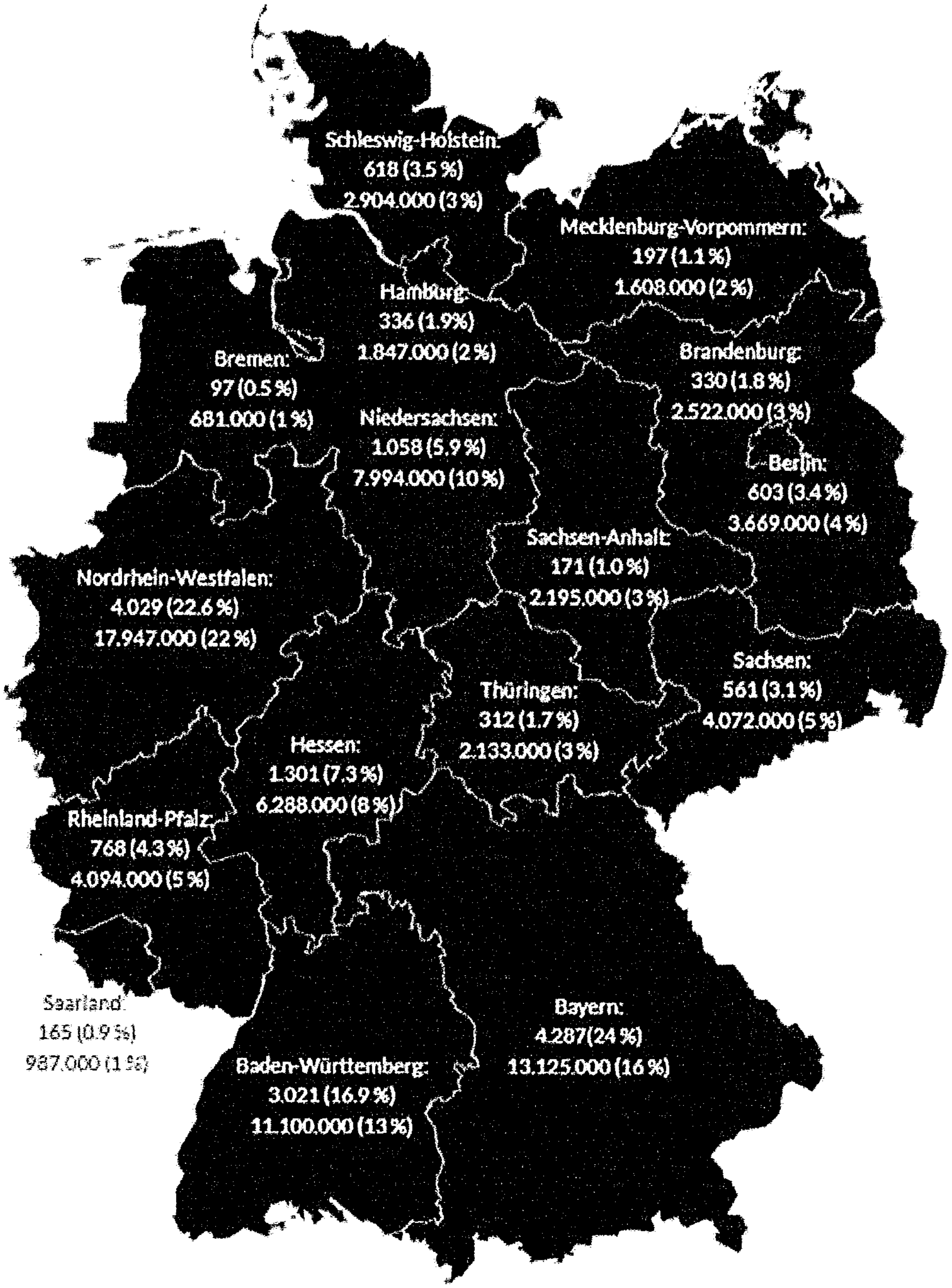
Schleswig-Holstein:
618 (3.5 %)
2.904.000 (3 %)
Mecklenburg-Vorpommern:
197 (1.1 %)
1.608.000 (2 %)
Hamburg:
336 (1.9%)
1.847.000 (2 %)
Bremen:
97 (0.5 %)
681.000 (1 %)
Niedersachsen:
1.058 (5.9 %)
7.994.000 (10 %)
Brandenburg:
330 (1.8 %)
2.522.000 (3 %)
Berlin:
603 (3.4 %)
3.669.000 (4 %)
Sachsen-Anhalt:
171 (1.0 %)
2.195.000 (3 %)
Nordrhein-Westfalen:
4.029 (22.6 %)
17.947.000 (22 %)
Sachsen:
561 (3.1 %)
4.072.000 (5 %)
Thüringen:
312 (1.7 %)
2.133.000 (3 %)
Hessen:
1.301 (7.3 %)
6.288.000 (8 %)
Rheinland-Pfalz:
768 (4.3 %)
4.094.000 (5 %)
Saarland:
165 (0.9 %)
987.000 (1 %)
Bayern:
4.287 (24 %)
13.125.000 (16 %)
Baden-Württemberg:
3.021 (16.9 %)
11.100.000 (13 %)

Figure 1

Distribution of participants by federal state. First row: Name of the federal state, second line: Parents in the registry, as absolute and relative frequency (as of 26.10.2020). Third line: Population in Germany in comparison, as absolute and relative frequency. The distribution of contributors corresponds approximately to the respective share of the population.

La neumonía bacteriana causó la mayoría de las muertes en la pandemia de influenza de 1918

Bacterial Pneumonia Caused Most Deaths in 1918 Influenza Pandemic https://www.nih.gov/news-events/news-releases/bacterial-pneumonia-caused-most-deaths-1918-influenza-pandemic DM Morens et al. Predominant role of bacterial pneumonia as a cause of death in pandemic influenza: Implications for pandemic influenza preparedness. *The Journal of Infectious Diseases* DOI: 10.1086/591708

La mayoría de las muertes durante la pandemia de influenza de 1918-1919 no fueron causadas por el virus de la influenza actuando solo, informan investigadores del Instituto Nacional de Alergias y Enfermedades Infecciosas (NIAID), parte de los Institutos Nacionales de Salud. En cambio, **la mayoría de las víctimas sucumbieron a la neumonía bacteriana después de la infección por el virus de la influenza**. La neumonía se produjo cuando las bacterias que normalmente habitan en la nariz y la garganta invadieron los pulmones a lo largo de una vía creada cuando el virus destruyó las células que recubren los bronquios y los pulmones.

Colabore con nosotros para que podamos subtitular este video,
gracias https://cienciaysaludnatural.com/colaboracion/

Una futura pandemia de influenza puede desarrollarse de manera similar, dicen los autores del NIAID, cuyo artículo en la edición del 1 de octubre de *The Journal of Infectious Diseases* ya está disponible en línea.

El trabajo presenta líneas de evidencia complementarias de los campos de la patología y la historia de la medicina para apoyar esta conclusión. "El peso de la evidencia que examinamos de los análisis históricos y modernos de la pandemia de influenza de 1918 favorece un escenario en el que **el daño viral seguido de neumonía bacteriana causó la**

gran mayoría de las muertes", dice el coautor del NIAID, Anthony S. Fauci, MD "En esencia, el virus dio el primer golpe mientras que las bacterias dieron el golpe de gracia". Ahora Fauci propone usar doble máscara con la supuesta pandemia del COVID-19.
El coautor y patólogo del NIAID, Jeffery Taubenberger, MD, Ph.D., examinó muestras de tejido pulmonar de 58 soldados que murieron de influenza en varias bases militares de EE. UU. En 1918 y 1919. Las muestras, conservadas en bloques de parafina, se volvieron a cortar y teñido para permitir la evaluación microscópica. El examen reveló un espectro de daño tisular "que va desde cambios característicos de la neumonía viral primaria y evidencia de reparación tisular hasta evidencia de neumonía bacteriana secundaria aguda, grave", dice el Dr. Taubenberger. En la mayoría de los casos, agrega, la enfermedad predominante en el momento de la muerte parecía haber sido la neumonía bacteriana. También hubo evidencia de que el virus destruyó las células que recubren los bronquios, incluidas las células con proyecciones protectoras similares a pelos o cilios.

En una búsqueda por obtener todas las publicaciones científicas que informan sobre la patología y bacteriología de la pandemia de influenza de 1918-1919, el Dr. Taubenberger y el coautor del NIAID, David Morens, MD, buscaron artículos en fuentes bibliográficas de cualquier idioma. También revisaron revistas científicas y médicas publicadas en inglés, francés y alemán, y localizaron todos los artículos que informaban sobre autopsias realizadas a víctimas de influenza. De un conjunto de más de 2.000 publicaciones que aparecieron entre 1919 y 1929**, los investigadores identificaron 118 informes clave de series de autopsias. En total, la serie de autopsias que revisaron representó 8.398 autopsias individuales realizadas en 15 países.**
Los informes publicados "implicaron clara y sistemáticamente la neumonía bacteriana secundaria causada por la flora respiratoria superior común en la mayoría de las muertes por influenza", dice el Dr. Morens. **Los patólogos de la época, agrega, fueron casi unánimes en la convicción de que las muertes no fueron causadas directamente por el virus de la influenza no identificado en ese momento, sino que fueron el resultado de una neumonía secundaria grave causada por varias bacterias.** Sin las infecciones bacterianas secundarias, muchos pacientes podrían haber sobrevivido, creían los expertos en ese momento. De hecho, la disponibilidad de antibióticos durante las otras pandemias de influenza del siglo XX, específicamente las de 1957 y 1968, fue probablemente un factor clave en el menor número de muertes en todo el mundo durante esos brotes, señala el Dr. Morens.
La causa y el momento de la próxima pandemia de influenza no se pueden predecir con certeza, reconocen los autores, ni tampoco la virulencia de la cepa del virus de la influenza pandémica. Sin embargo, es posible que, como en 1918, se desarrolle un patrón similar de daño viral seguido de invasión bacteriana, dicen los autores. Los preparativos para

diagnosticar, tratar y prevenir la neumonía bacteriana deben estar entre las más altas prioridades en la planificación de una pandemia de influenza, escriben.

Acerca de los Institutos Nacionales de Salud (NIH): NIH, la agencia de investigación médica del país, incluye 27 institutos y centros y es un componente del Departamento de Salud y Servicios Humanos de EE. UU. NIH es la principal agencia federal que realiza médica básica, clínica y traslacional, y está investigando las causas, tratamientos y curas para enfermedades comunes y raras.

Referencias:

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Pandemic https://www.nih.gov/news-events/news-releases/bacterial-pneumonia-caused-most-deaths-1918-influenza-pandemic

https://cienciaysaludnatural.com/la-neumonia-bacteriana-causo-la-mayoria-de-las-muertes-en-la-pandemia-de-influenza-de-1918/

Commentary: Estimating the effects of non-pharmaceutical interventions on COVID-19 in Europe

Christof Kuhbandner[1*] and Stefan Homburg[2]

- [1]Department of Human Sciences, University of Regensburg, Regensburg, Germany
- [2]Department of Public Finance, Leibniz University Hannover, Hannover, Germany

A Commentary on
Estimating the effects of non-pharmaceutical interventions on COVID-19 in Europe

by Flaxman, S., Mishra, S., Gandy, A., Unwin, H. J. T., Mellan, T. A., Coupland, H., et al. (2020). Nature 584, 257–261. doi: 10.1038/s41586-020-2405-7

A key concept in epidemiology is the effective reproduction number, $R(t)$, where t denotes time. This function represents the expected number of infections generated by one infected individual. Ceteris paribus, the effective reproduction number starts at $R(0)$, referred to as the basic reproduction number, and decreases monotonically. The monotonic decrease is due to the fact that the number of individuals susceptible to the infection but not yet infected declines as the virus spreads. Of course, the function $R(t)$ can be influenced by non-pharmaceutical interventions (NPIs) as well as by voluntary behavioral changes. However, in case of a finite population, the effective reproduction number falls automatically and necessarily over time since the number of infections would otherwise diverge. For recent discussions of the *R*(*t*), see (1, 2).

The model of Flaxman et al. (3) contradicts this elementary insight. They estimate *R*(*t*) from daily deaths associated with SARS-CoV-2 using as an *a priori* restriction that *R*(*t*) may *only* change at those dates where interventions become effective. Such an approach does not prove that NPIs were effective but rather begs the result, i.e., involves circular logic. The true effective reproduction number declines continuously, and when its estimates are allowed to change only at intervention points, it is clear that profound discontinuities, which attribute strong effects to the interventions, will emerge. Flaxman et al. (p. 2) conclude that while most NPIs had unidentifiable effects, lockdowns reduced the reproduction numbers instantaneously by 82%. Taking the United Kingdom as an example, Figure 1A illustrates the ineffectiveness of social distancing, etc. in the analysis of Flaxman et al. as well as the enormous effect of the lockdown from 23 March.

FIGURE 1

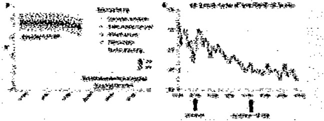

Figure 1. (A) Estimate of the effective reproduction number by Flaxman et al. [(3), Figure 1]. The authors assumed *R*(*t*) to be constant before 14 March and after 23 March. Changes were allowed only on the four dates where NPIs became effective. **(B)** Growth factor of daily deaths.
Source: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/891710/2020-06-11_COVID-19_UK_deaths_time_series.csv. Moving averages, 7 days. Retrieved 14 June 2020. Given daily deaths d_t, growth factors were computed as d_t/d_{t-1}. Note that if daily deaths show exponential growth, any moving average will also show exponential growth.

Flaxman et al. (p. 2) infer their estimate of the basic reproduction number from the initial growth of reported daily deaths. Figure 1B shows the actual growth of reported daily deaths. In both cases, the growth factors considered are defined as d_t/d_{t-1}, where d_t represents the number of fatalities reported for day t. Following the presumption of Flaxman et al. that deaths are more reliable than cases, we see the growth factors of daily deaths as a good empirical proxy that mirrors the development of the effective reproduction rate. Of course, deaths follow infections after a long delay—a fact that is taken into account below.

Disregarding noise in the data, the growth in daily deaths associated with the coronavirus declined steadily during March and April. Moreover, reported daily deaths follow infections with a median delay of 23 days, consisting of a 5-day incubation period (4) and a median delay of about 18 days from symptom onset to death (5). Note that this delay also underlies the estimations by Flaxman et al. (p. 22 of their supplementary information). In a recent paper, Wood (6) estimates a longer delay of 26.8 days for UK. We do not use this estimate because it was not available for Flaxman et al. but note that taking account of the longer delay would even strengthen our point.

Considering a total delay of 23 days between infection and death, possible effects of the 23 March lockdown should only become visible in the data around April 15. However, the series does not show the slightest break in mid-April. Hitherto, the growth factor had already declined from 1.54 to 0.97, and thereafter it continued its slowdown. Quite contrary to the findings of Flaxman et al. Figure 1B strongly suggests that the UK lockdown was both superfluous (it did not prevent an otherwise explosive behavior of the spread of the coronavirus) and ineffective (it did not slow down the death growth rate visibly).

The argument of a delay of 23 days between infection and death can also be used in the opposite direction. With the growth rate of daily corona deaths falling since mid-March, the underlying growth rate of daily infections must have started receding in the second half of February, long before the problem was recognized and any measures were taken. The continuous decrease in the growth factor shown in Figure 1B, even at dates before any NPI could have become effective, corroborates the theoretical insight that $R(t)$ falls automatically over time. We have checked that the growth factors in the remaining 10 countries considered by Flaxman et al. show a similar pattern. Our analysis does not answer the question whether the decrease of $R(t)$ was due to a decreasing number of susceptible persons or to voluntary behavioral changes, but it rules out the possibility that the decrease was caused by the general lockdown.

Our final remark regards Sweden, the only country in the dataset that refrained from strong measures, but has lower corona deaths per capita than Belgium, Italy, Spain, or the United Kingdom. In the absence of a lockdown, but with an effective reproduction number that declined in the usual fashion, Flaxman et al. (Extended Data Figure 1) attribute the sudden decline in Sweden's $R(t)$ on March 27 almost entirely to banning of public events, i.e., to a NPI that they found ineffective in all other countries. This inconsistency underlines our contention that the results of Flaxman et al. are artifacts of an inappropriate model.

Author Contributions

CK and SH co-wrote the paper.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Acknowledgments

This manuscript has been released as a pre-print at advance (7).

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PubMed Abstract | Google Scholar

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Google Scholar

Keywords: SARS-CoV-2, COVID-19, non-pharmaceutical interventions, mitigation strategies, epidemiology

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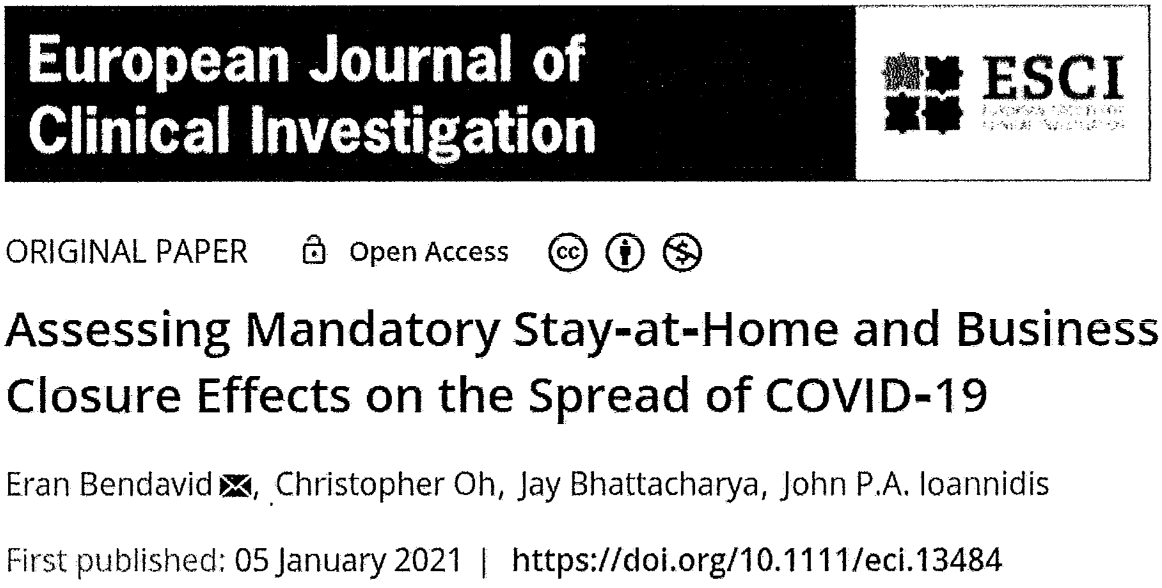
***Correspondence:** Christof Kuhbandner, **christof.kuhbandner@ur.de**

https://www.frontiersin.org/articles/10.3389/fmed.2020.580361/full

30 ESTUDIOS DEMOSTRANDO QUE LAS CUARENTENAS NO DAN LOS RESULTADOS ESPERADOS

A continuación se encuentran 30 estudios demostrando que las cuarentenas no dan los resultados esperados, no disminuyen la mortalidad, son mucho más dañinas para la salud pública de lo que el COVID-19 puede ser.

01



European Journal of Clinical Investigation
ESCI

ORIGINAL PAPER Open Access

Assessing Mandatory Stay-at-Home and Business Closure Effects on the Spread of COVID-19

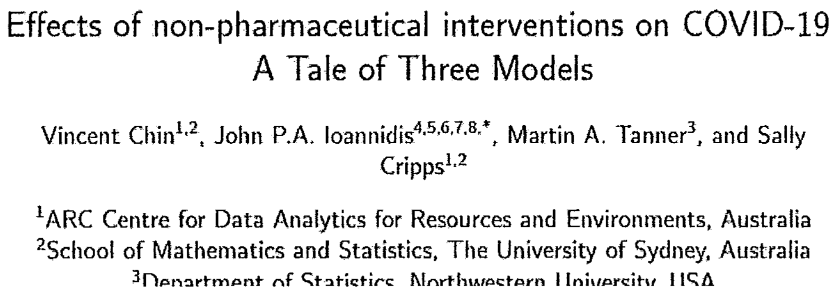
Eran Bendavid, Christopher Oh, Jay Bhattacharya, John P.A. Ioannidis

First published: 05 January 2021 | https://doi.org/10.1111/eci.13484

> *"No hay evidencia de que las intervenciones no farmacéuticas más restrictivas (" bloqueos ") hayan contribuido sustancialmente a doblar la curva de nuevos casos en Inglaterra, Francia, Alemania, Irán, Italia, los Países Bajos, España o los Estados Unidos a principios de 2020"*

LINK (Eran Bendavid et al)

02



Effects of non-pharmaceutical interventions on COVID-19: A Tale of Three Models

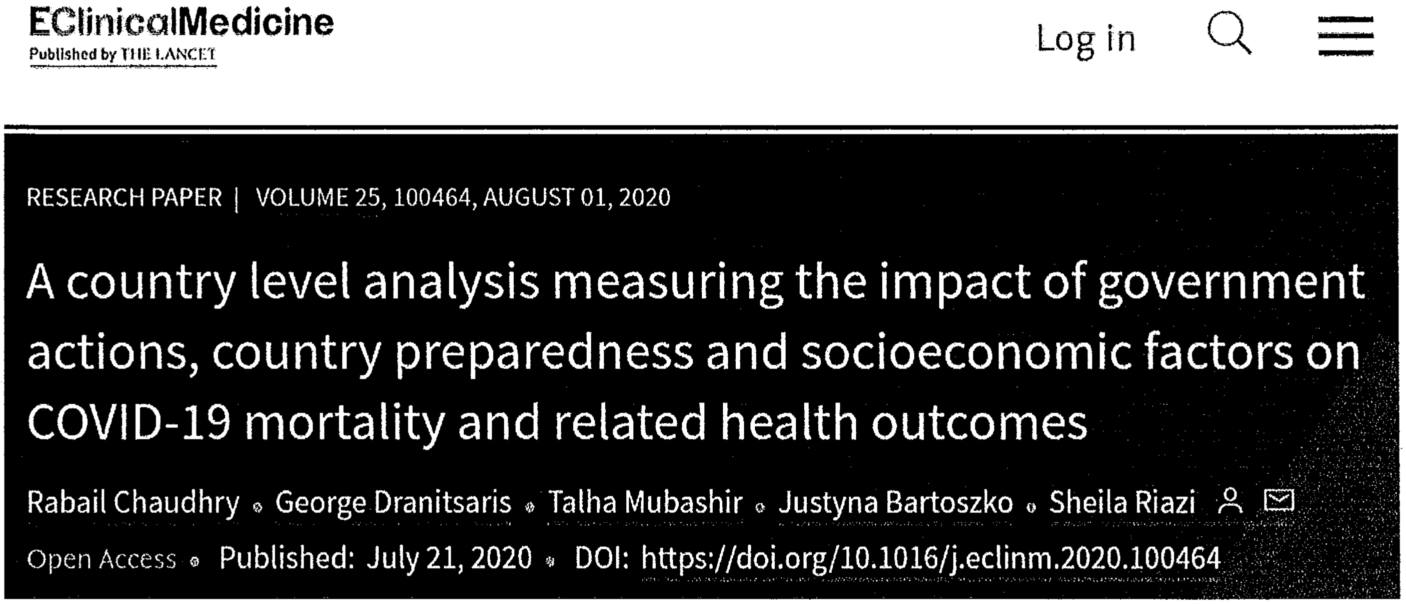
Vincent Chin[1,2], John P.A. Ioannidis[4,5,6,7,8,*], Martin A. Tanner[3], and Sally Cripps[1,2]

[1]ARC Centre for Data Analytics for Resources and Environments, Australia
[2]School of Mathematics and Statistics, The University of Sydney, Australia
[3]Department of Statistics, Northwestern University, USA

> *"Las inferencias sobre los efectos de las non-pharmaceutical interventions, NPI no son sólidas y muy sensibles a la especificación del modelo. Los supuestos beneficios del encierro parecen tremendamente exagerados ".*

ENLACE (John PA Ioannidis et al)

03



RESEARCH PAPER | VOLUME 25, 100464, AUGUST 01, 2020

A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes

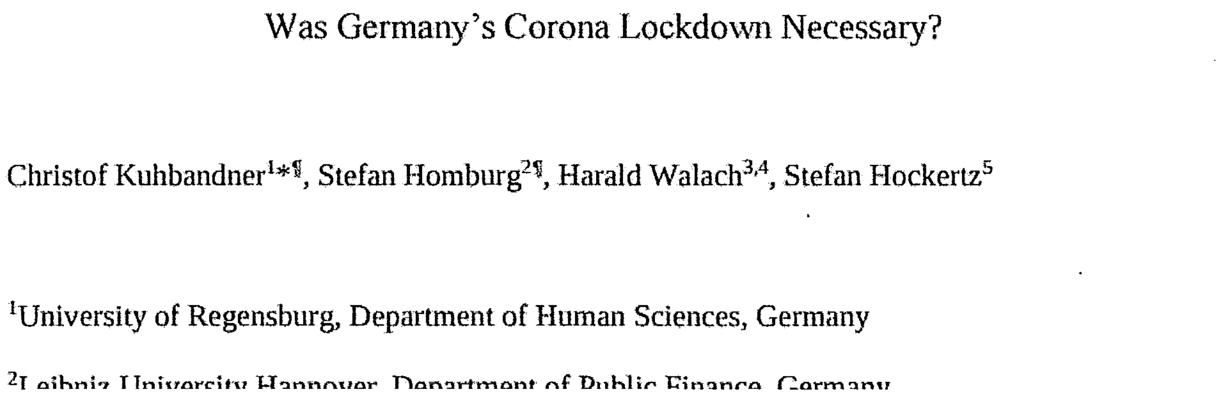
Rabail Chaudhry • George Dranitsaris • Talha Mubashir • Justyna Bartoszko • Sheila Riazi

Open Access • Published: July 21, 2020 • DOI: https://doi.org/10.1016/j.eclinm.2020.100464

> *"Las acciones gubernamentales como el cierre de fronteras, los bloqueos totales y una alta tasa de pruebas de COVID-19 no se asociaron con reducciones estadísticamente significativas en el número de casos críticos o la mortalidad general"*

ENLACE (Rabail Chaudhrya et al)

04



Was Germany's Corona Lockdown Necessary?

Christof Kuhbandner[1*¶], Stefan Homburg[2¶], Harald Walach[3,4], Stefan Hockertz[5]

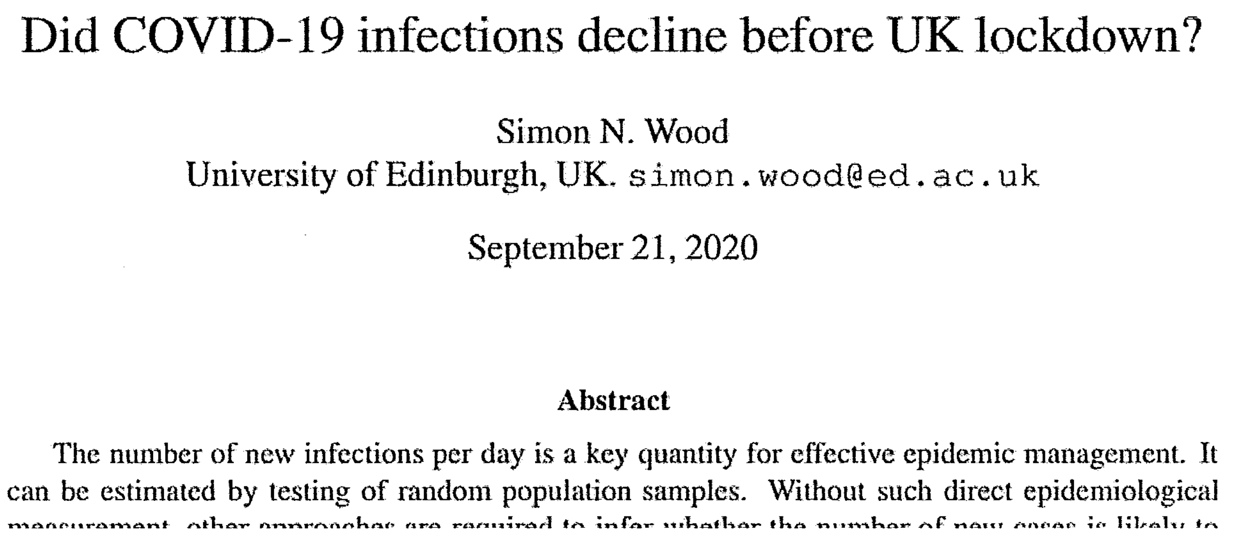
[1]University of Regensburg, Department of Human Sciences, Germany

[2]Leibniz University Hannover, Department of Public Finance, Germany

> *"Los datos oficiales de la agencia RKI de Alemania sugieren firmemente que la propagación del coronavirus en Alemania retrocedió de forma autónoma, antes de que cualquier intervención se hiciera efectiva".*

LINK (Christof Kuhbandner et al)

05



Did COVID-19 infections decline before UK lockdown?

Simon N. Wood
University of Edinburgh, UK. `simon.wood@ed.ac.uk`

September 21, 2020

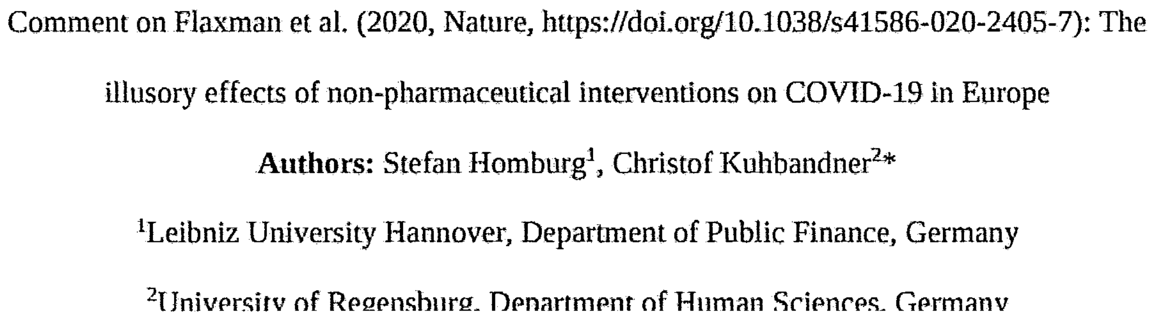
Abstract

The number of new infections per day is a key quantity for effective epidemic management. It can be estimated by testing of random population samples. Without such direct epidemiological

> *"La disminución de las infecciones en Inglaterra ... comenzó antes del bloqueo total ... [E] ucho un escenario sería consistente con ... Suecia, que comenzó su disminución de las infecciones fatales poco después del Reino Unido, pero lo hizo sobre la base de medidas muy por debajo del bloqueo total "*

ENLACE (Simon N. Wood)

06



Comment on Flaxman et al. (2020, Nature, https://doi.org/10.1038/s41586-020-2405-7): The illusory effects of non-pharmaceutical interventions on COVID-19 in Europe

Authors: Stefan Homburg[1], Christof Kuhbandner[2]*

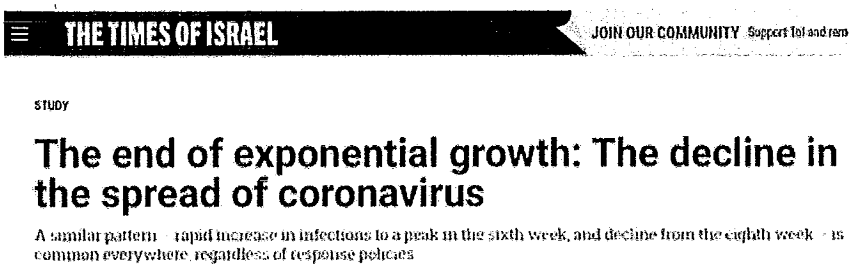
[1]Leibniz University Hannover, Department of Public Finance, Germany

[2]University of Regensburg, Department of Human Sciences, Germany

> *"El bloqueo del Reino Unido fue superfluo (no evitó un comportamiento explosivo de la propagación del coronavirus) e ineficaz (no ralentizó visiblemente la tasa de crecimiento de la muerte)".*

ENLACE (Stefan Homburg et al)

07



STUDY

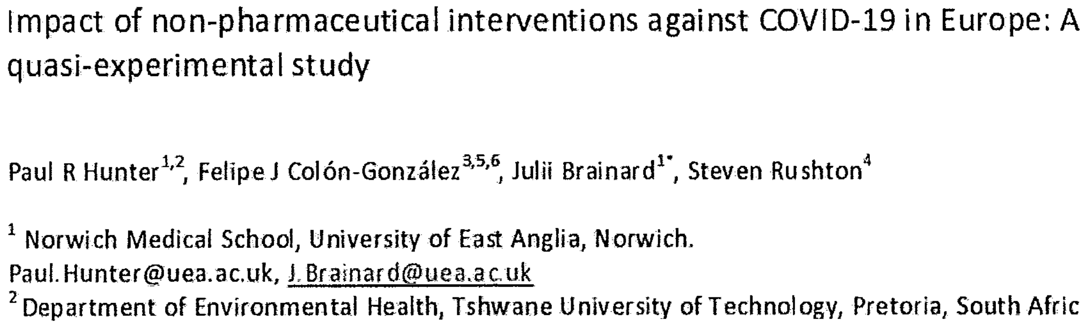
The end of exponential growth: The decline in the spread of coronavirus

A similar pattern – rapid increase in infections to a peak in the sixth week, and decline from the eighth week – is common everywhere, regardless of response policies

> *"Dado que la evidencia revela que la enfermedad de Corona disminuye incluso sin un bloqueo completo, es recomendable revertir la política actual y eliminar el bloqueo"*

LINK (ISAAC BEN-ISRAEL)

08



Impact of non-pharmaceutical interventions against COVID-19 in Europe: A quasi-experimental study

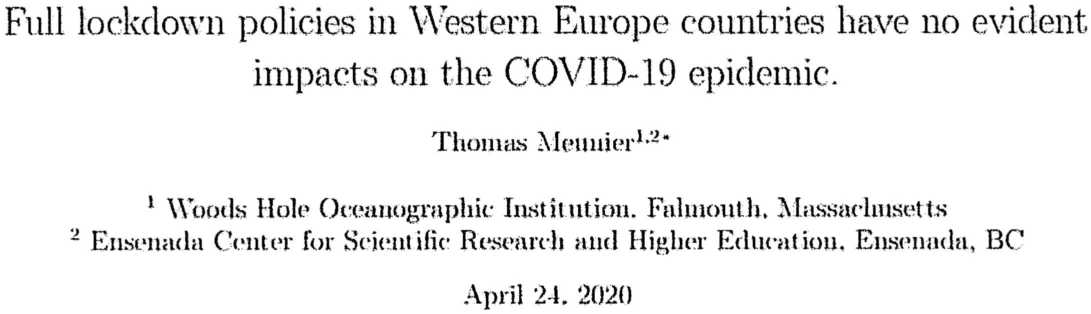
Paul R Hunter[1,2], Felipe J Colón-González[3,5,6], Julii Brainard[1*], Steven Rushton[4]

[1] Norwich Medical School, University of East Anglia, Norwich.
Paul.Hunter@uea.ac.uk, J.Brainard@uea.ac.uk
[2] Department of Environmental Health, Tshwane University of Technology, Pretoria, South Afric

> *"Los pedidos para quedarse en casa, el cierre de todos los negocios no esenciales y la necesidad de usar máscaras o cubrimientos en público no se asoció con ningún impacto adicional independiente"*

ENLACE (Paul R Hunter et al)

09



Full lockdown policies in Western Europe countries have no evident impacts on the COVID-19 epidemic.

Thomas Meunier[1,2*]

[1] Woods Hole Oceanographic Institution, Falmouth, Massachusetts
[2] Ensenada Center for Scientific Research and Higher Education, Ensenada, BC

April 24, 2020

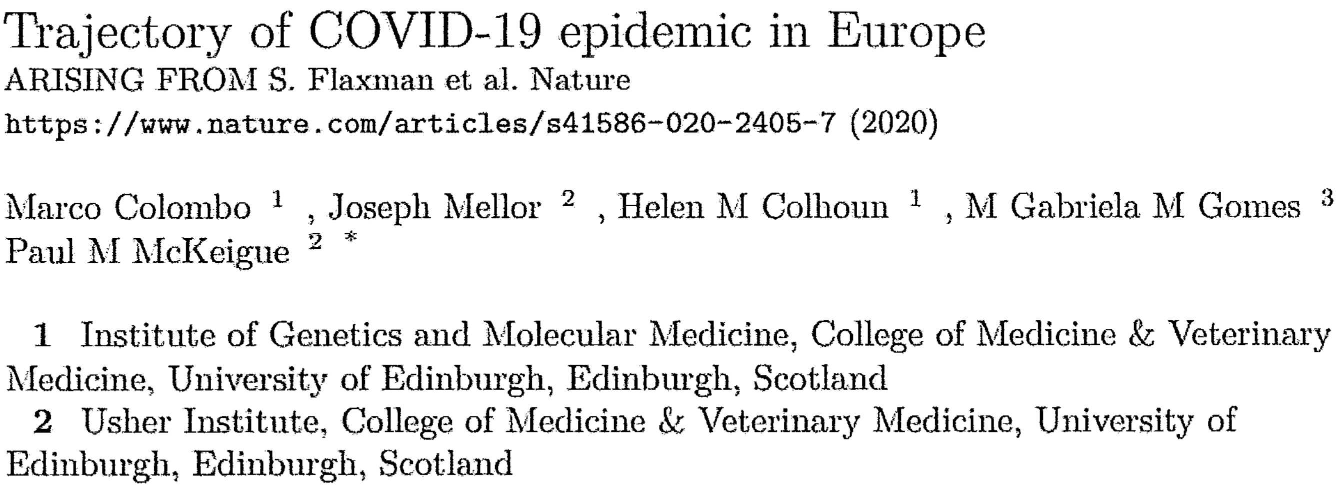
> *"Es posible que estas estrategias no hayan salvado ninguna vida en Europa occidental. También mostramos que los países vecinos que aplican medidas de distanciamiento social menos restrictivas ... experimentan una evolución temporal de la epidemia muy similar ".*

> *"Dado que se ha demostrado que las estrategias de bloqueo total no tienen ningún impacto en la desaceleración de la epidemia, se debe considerar su número de muertes inherente potencialmente alto como una pérdida neta de*

> *vidas humanas"*

ENLACE (Thomas Meunier)

10



Trajectory of COVID-19 epidemic in Europe

ARISING FROM S. Flaxman et al. Nature
`https://www.nature.com/articles/s41586-020-2405-7` (2020)

Marco Colombo [1] , Joseph Mellor [2] , Helen M Colhoun [1] , M Gabriela M Gomes [3]
Paul M McKeigue [2] *

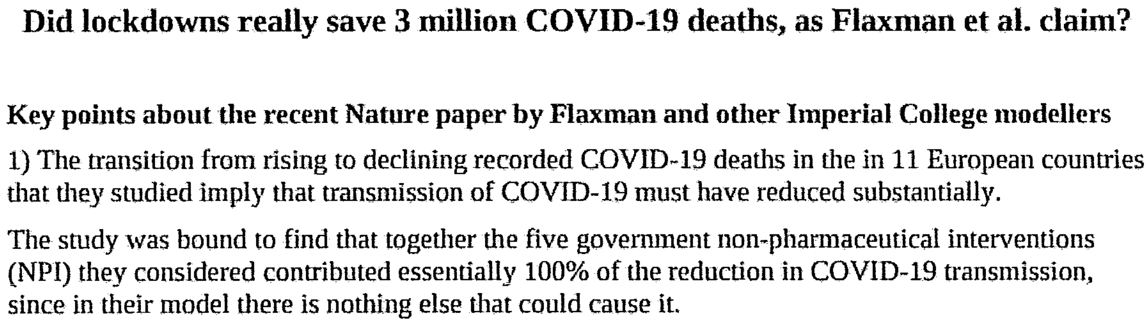
1 Institute of Genetics and Molecular Medicine, College of Medicine & Veterinary Medicine, University of Edinburgh, Edinburgh, Scotland
2 Usher Institute, College of Medicine & Veterinary Medicine, University of Edinburgh, Edinburgh, Scotland

> *"El modelo no respalda [la] estimación de que el bloqueo redujo el número de reproducción de casos R en un 81% o que más de tres millones de muertes se evitaron mediante intervenciones no farmacéuticas".*

(Refiriéndose al artículo de Nature de Flaxman y otros modeladores del Imperial College)

LINK (Marco Colombo et al)

11



Did lockdowns really save 3 million COVID-19 deaths, as Flaxman et al. claim?

Key points about the recent Nature paper by Flaxman and other Imperial College modellers

1) The transition from rising to declining recorded COVID-19 deaths in the in 11 European countries that they studied imply that transmission of COVID-19 must have reduced substantially.

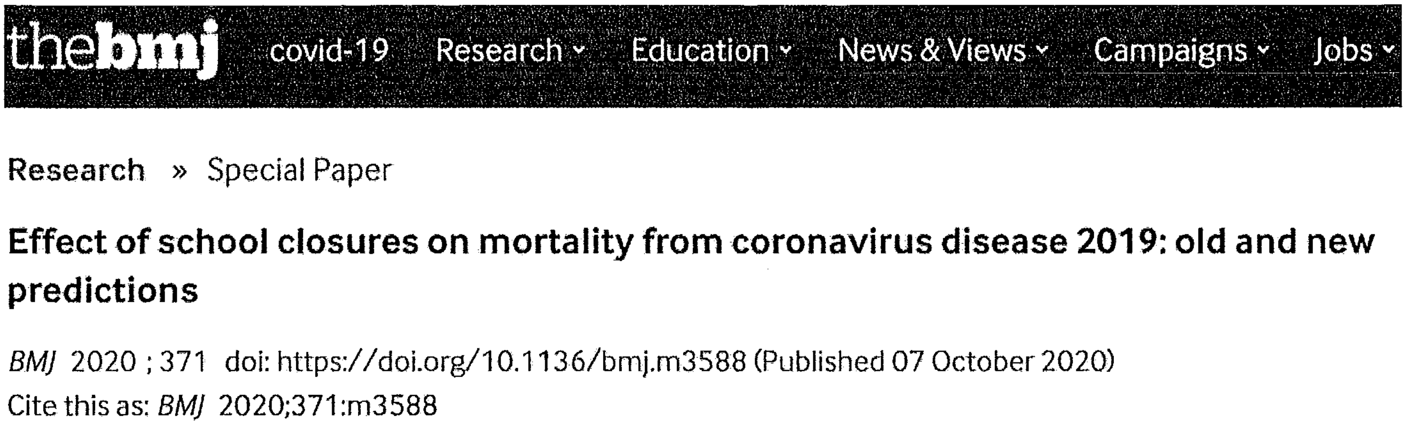
The study was bound to find that together the five government non-pharmaceutical interventions (NPI) they considered contributed essentially 100% of the reduction in COVID-19 transmission, since in their model there is nothing else that could cause it.

> *"El caso de Suecia, donde los autores encuentran que la reducción en la transmisión ha sido solo moderadamente más débil que en otros países a pesar de que no se ha producido ningún bloqueo, es una prueba prima facie contra la afirmación principal del artículo".*

(Refiriéndose al artículo de Nature de Flaxman y otros modeladores del Imperial College)

ENLACE (Nicholas Lewis)

12



Research » Special Paper

Effect of school closures on mortality from coronavirus disease 2019: old and new predictions

BMJ 2020 ; 371 doi: https://doi.org/10.1136/bmj.m3588 (Published 07 October 2020)
Cite this as: *BMJ* 2020;371:m3588

> *"Los resultados presentados en el informe sugirieron que la adición de intervenciones que restringen a las personas más jóvenes en realidad podría aumentar el número total de muertes por covid-19"*

ENLACE (Ken Rice et al)

13

Modeling social distancing strategies to prevent SARS-CoV2 spread in Israel- A Cost-effectiveness analysis

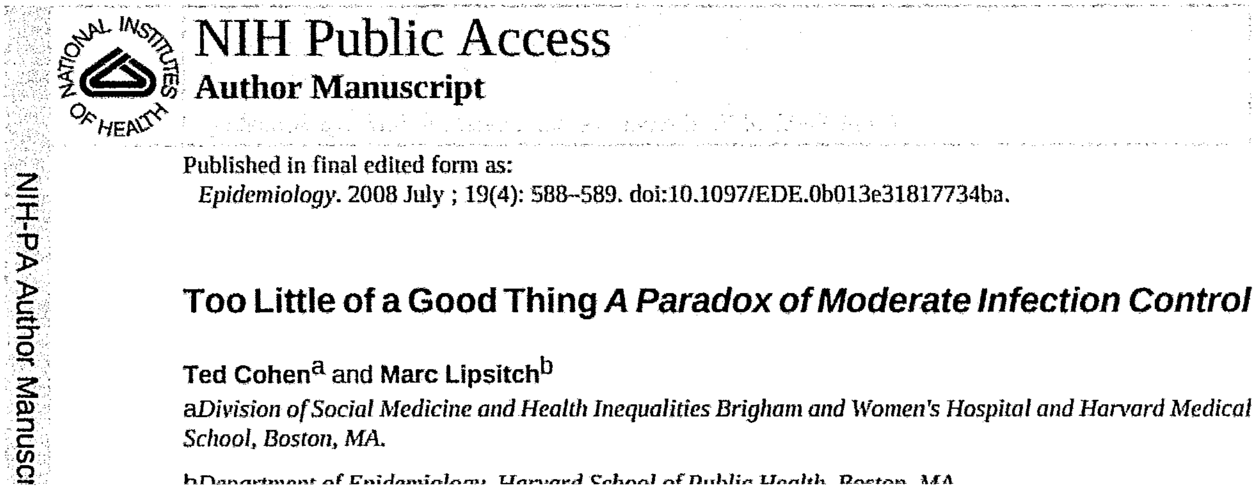
Amir Shlomai MD, PhD[1], Ari Leshno MD[2], Ella H. Sklan PhD[3]*+, Moshe Leshno MD, PhD[4]*

[1] Department of Medicine D and The Liver Institute, Rabin Medical Center,
Beilinson Hospital, Petah-Tikva, Israel and The Sackler Faculty of Medicine, Tel Aviv

> *"Demostramos que [el encierro] es modestamente superior para salvar vidas en comparación con [la protección enfocada], pero con enormes costos para prevenir un caso de muerte. Esto podría resultar en efectos económicos abrumadores que se espera que aumenten el número de muertes en el futuro"*

LINK (Amir Shlomai, et al)

14



NIH-PA Author Manuscript

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Epidemiology. 2008 July ; 19(4): 588–589. doi:10.1097/EDE.0b013e31817734ba.

Too Little of a Good Thing ***A Paradox of Moderate Infection Control***

Ted Cohen[a] and **Marc Lipsitch**[b]

aDivision of Social Medicine and Health Inequalities Brigham and Women's Hospital and Harvard Medical School, Boston, MA.

bDepartment of Epidemiology, Harvard School of Public Health, Boston, MA

> *"Para los patógenos que causan una mayor morbilidad a edades más avanzadas, las intervenciones que reducen pero no eliminan la exposición pueden, paradójicamente, aumentar el número de casos de enfermedad grave al trasladar la carga de la infección hacia las personas mayores"*

LINK (Ted Cohen et al)

15

Smart Thinking, Lockdown and COVID-19: Implications for Public Policy

Journal of Behavioral Economics for Policy, 2020

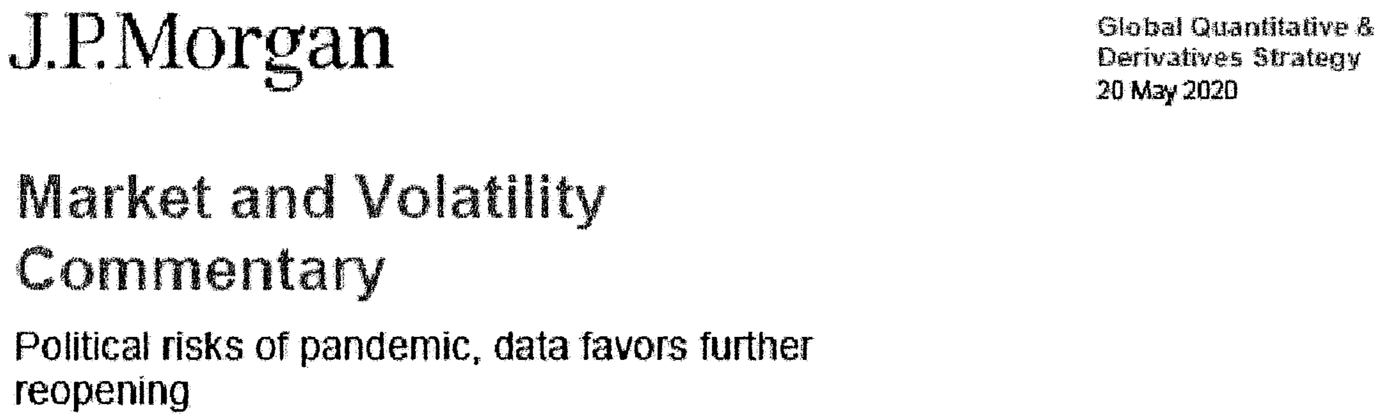
Posted: 26 May 2020

Morris Altman
University of Dundee

> *"La política actual [abrumadoramente hacia el encierro] puede estar mal encaminada y con efectos muy negativos en el bienestar humano. Además, tales políticas pueden resultar inadvertidamente en no minimizar las tasas de muerte en absoluto, (incorporando externalidades) especialmente a largo plazo"*

ENLACE (Morris Altman)

16



J.P.Morgan

Global Quantitative &
Derivatives Strategy
20 May 2020

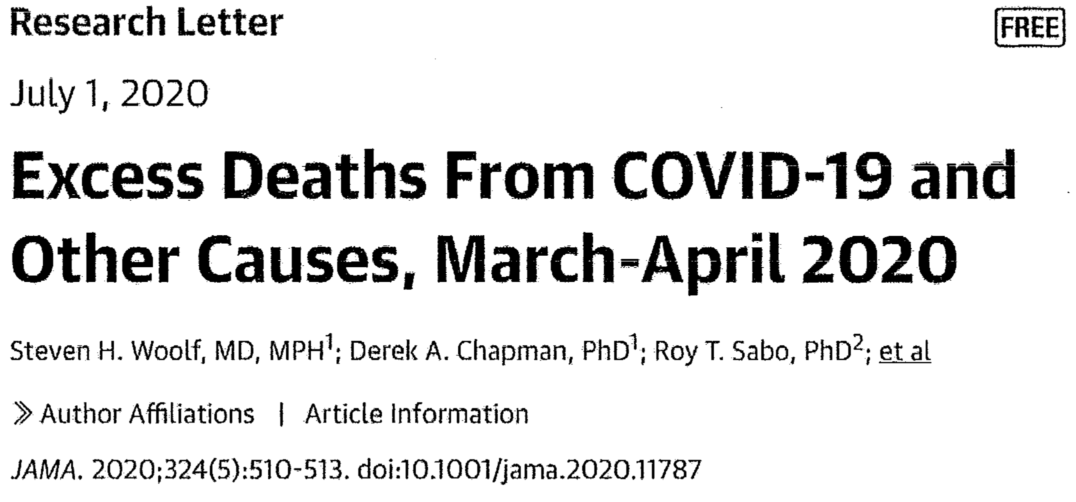
Market and Volatility Commentary

Political risks of pandemic, data favors further reopening

> *"Por ejemplo, los datos ... muestran una disminución en las tasas de infección después de que los países suavizaron ... cierres con> 99% de significación estadística. De hecho ... las tasas de infección han disminuido después de reabrir incluso después de permitir un retraso de medición apropiado. Esto significa que el La pandemia y el COVID-19 probablemente tengan sus propias dinámicas no relacionadas con las medidas de bloqueo a menudo inconsistentes que se estaban implementando ".*

ENLACE (Marko Kolanovic et al)

17



Research Letter

FREE

July 1, 2020

Excess Deaths From COVID-19 and Other Causes, March-April 2020

Steven H. Woolf, MD, MPH[1]; Derek A. Chapman, PhD[1]; Roy T. Sabo, PhD[2]; et al

» Author Affiliations | Article Information

JAMA. 2020;324(5):510-513. doi:10.1001/jama.2020.11787

> *"las restricciones impuestas por la pandemia (p. ej., órdenes de quedarse en casa) podrían cobrar vidas indirectamente a través de la atención tardía en emergencias agudas, exacerbaciones de enfermedades crónicas y angustia psicológica (p. ej., sobredosis de drogas)"*

> ***"más del 50% del exceso de muertes se atribuyó a causas subyacentes distintas de COVID-19; estas incluyeron California (55% del exceso de muertes) y Texas (64% del exceso de muertes)"***

ENLACE (Steven H. Woolf et al)

18

medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES

Cold Spring Harbor Laboratory
BMJ
Yale
Comment

SARS-CoV-2 waves in Europe: A 2-stratum SEIRS model solution

> *“Descubrimos que 180 días de aislamientos obligatorios para sanos <60 (es decir, escuelas y lugares de trabajo cerrados) producen más muertes finales si la fecha de vacunación es posterior a (Madrid: 23 de febrero de 2021; Cataluña: 28 de diciembre de 2020; París: 14 de enero de 2021 ; Londres: 22 de enero de 2021) “*

LINK (Levan Djaparidze et al)

19

> *“Al comparar la mortalidad semanal en 24 países europeos, los hallazgos de este documento sugieren que* ***las políticas de bloqueo más severas no se han asociado con una menor mortalidad****. En otras palabras, los bloqueos no han funcionado como se esperaba”*

ENLACE (Christian Bjørnskov)

20

> *"[el] presidente ... ha negado rotundamente la gravedad de la pandemia, negándose a imponer un cierre, cerrar escuelas o cancelar eventos masivos ... Sin embargo, la tasa de mortalidad del país se encuentra entre las más bajas de Europa, algo más de 700 en una población de 9,5 millones "*

ENLACE (Dijo Karáth)

21

> *"vivir con niños de 0 a 11 años no se asoció con un mayor riesgo de infección registrada por SARS-CoV-2, hospitalización relacionada con COVID-19 o ingreso en la UCI, pero se asoció con un* ***riesgo reducido de muerte por COVID-19****"*

> ***"Nuestros resultados no demuestran evidencia de daños graves por COVID-19 a adultos en contacto cercano con niños, en comparación con aquellos que viven en hogares sin niños".***

ENLACE (Harriet Forbes et al)

22

375

> *“De acuerdo con las observaciones de que … no se ha observado que el bloqueo afecte significativamente la tasa … de las tasas de reproducción del país, nuestro análisis sugiere que no hay base para esperar que la rigurosidad del bloqueo sea una variable explicativa”*

ENLACE (Nick Hudson et al)

23

> *“Este estudio muestra que el virus ya está aquí, y debemos encontrar formas de vivir con él de manera que no haya causado pérdidas humanas y socioeconómicas mínimas o nulas en … Nigeria en su conjunto … volver al bloqueo nunca debería ser entretenido “*

ENLACE Hussaini Majiya et al)

24

> *"los reclutas estaban bajo la supervisión constante de los instructores de la Infantería de Marina. Es poco probable que otros entornos en los que se congregan los adultos jóvenes reflejen una adherencia similar a las medidas destinadas a reducir la transmisión"*

> *"Nuestro estudio mostró que en un grupo de reclutas militares predominantemente hombres jóvenes, aproximadamente el 2% se volvió positivo para el SARS-CoV-2, según lo determinado por el ensayo qPCR, durante una cuarentena de 2 semanas estrictamente aplicada".*

ENLACE (Andrew G. Letizia, MD et al)

25

> *"Los criterios nacionales más asociados con la tasa de mortalidad son la esperanza de vida y su desaceleración, el contexto de salud pública (carga de enfermedades metabólicas y no transmisibles (ENT) frente a la prevalencia de enfermedades infecciosas), la economía (crecimiento del producto nacional, apoyo financiero) y el medio ambiente (temperatura, índice ultravioleta).*

> ***El rigor de las medidas establecidas para combatir la pandemia, incluido el encierro, no pareció estar relacionado con la tasa de mortalidad "***

ENLACE (Quentin De Larochelambert et al)

26

> *"El hecho de que un condado haya tenido un bloqueo no tiene ningún efecto sobre las muertes por Covid-19; un efecto que no persiste en el tiempo. Los estudios entre países también encuentran que los* ***bloqueos son superfluos e ineficaces*** *(Homberg 2020). Esta ineficacia puede tener varias causas".*

ENLACE (John Gibson et al)

27

> *"No hay observaciones históricas ... que apoyen ... el confinamiento por cuarentena de grupos de personas posiblemente infectadas por períodos prolongados ... Las consecuencias negativas ... son tan extremas ...* ***esta mitigación ... debe eliminarse de una consideración seria*** *"*

LINK (Thomas V. Inglesby et al)

28

> *"presentamos datos que demuestran que la mortalidad debida al covid-19 ... podría haberse predicho en gran medida incluso antes de que la pandemia golpeara Europa, simplemente observando la variabilidad longitudinal de las tasas de mortalidad por todas las causas en los años anteriores al ... brote"*

> *"Los* ***factores que impulsaron el exceso de mortalidad en 2020 ya estaban presentes en 2015-2019, es decir, durante un período en el que no se tomaron medidas*** *en ningún país"*

ENLACE (Jon O. Lundberg et al)

29

> *"Nuestro análisis muestra que si bien los niveles de infección disminuyeron, lo hicieron antes de que el cierre fuera efectivo, y el número de infecciones también disminuyó en los municipios vecinos sin mandatos".*

> *"Los datos sugieren que la vigilancia eficaz de las infecciones y el cumplimiento voluntario hacen que* ***los bloqueos completos sean innecesarios*** *al menos en algunas circunstancias".*

LINK (Kasper Planeta Kepp et al)

30

> *"En tercer lugar, describo cómo la realidad comenzó a asimilarse, con información sobre daños colaterales significativos debido a la respuesta a la pandemia e información que coloca el número de muertes en contexto y perspectiva.*

> *Cuarto, presento un análisis de costo-beneficio de la respuesta al COVID-19 que encuentra que* ***los bloqueos son mucho más dañinos para la salud pública de lo que el COVID-19 puede ser*** *"*

LINK (Ari R Joffe, noviembre de 2020)

31

Calling for benefit–risk evaluations of COVID-19 control measures

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00193-8/fulltext

380

Countering the Second Wave with Facts, not Misconceptions

Udi Qimron, Uri Gavish, Eyal Shahar, Michael Levitt

On March of this year, the UK government seriously considered avoiding a lockdown, but changed its mind abruptly after mathematical models, presented by Prof. Neil Ferguson, predicted baseless doomsday scenarios. The same type of models predicted that in Sweden, the number of deaths from COVID-19 would reach about 100,000 by June, if the Swedish government continues to refuse to impose lockdown measures. Sweden rejected these models and bravely adopted, although with certain initial failures, a democratic policy that broadly enabled normal life to continue.

Despite the large nursing homes in Sweden, insufficient early protection measures for them, and in stark contrast to apocalyptic forecasts – the number of deaths turned out to be 6% of the one predicted, about 6,000 people, at an average age of 81. Half of the victims were nursing home residents who, in Sweden, have a median life expectancy of 9 months after admission. If a similar policy were to be adopted in Israel, for example, this figure of 6,000 places an upper limit of 3,000 deaths, because the size of the Swedish elderly population is more than double that of Israel. For comparison, more than 4,000 people who contract pneumonia die in Israel every year – that is, an average of more than 10 people per day.

The spread of the COVID-19 epidemic in Sweden has reached its saturation point without fulfilling the well-known, but erroneous, threshold of infecting 60% of the total population – the presumed required level for herd immunity. How did this happen?

Contrary to a popular belief, the Swedish policy did not set the goal of causing as many people as possible to become infected. Its goal was, and still is, to enable a sustainable degree of normal life, while recommending that vulnerable people take precautions and allowing others to be exposed to the virus and develop immunity. The latter, who made up less than 20 percent of the population, complemented the natural immunity to the virus that already existed in the population, thus arresting its spread.

Israel and other countries that face a second wave can adopt a policy similar to Sweden, or even better. Such a policy may provide a fast exit from the crisis and reduce the number of victims. We first list counter-arguments.

Three arguments against exposing low-risk population to the virus

1. Acquired immunity following infection is short-lasting, and therefore should not be relied on.
2. In order to reach the saturation point of the spread of the infection, 60% of the population must be infected – an intolerable percentage.
3. The death toll of such a policy will be higher than the death toll of the alternative – namely, cyclic imposition and easing of restrictions, according to observed rates of infection.

We unequivocally reject these arguments because scientific evidence indicates that the exact opposite is true. All three are based on misconceptions, and those who have conceived these fallacies continue to hold on to them, leading many countries to human-made catastrophe. We refute each argument next.

Infection with COVID-19 results in long-term immunity

The first argument – infection does not result in long-term immunity – stems from incorrect reports about re-infection in people who have recovered from a first one. Dozens of cases of re-infection were discovered in South Korea several months ago and caused a great deal of panic. All of these recurrent infections turned out to be testing errors (falsely positive) due to inability of the standard PCR test to distinguish between a live virus and its residual genetic material. Of more than 20 million people infected, only few cases of re-infection have been reported and the possibility of a testing error has never been properly excluded. That almost no re-infections have yet been established after millions of infections overwhelmingly indicates that immunity is effective for at least 8 months after infection (the time since viral emergence). We see no reason to assume that immunity to COVID-19 will fade away quickly, since immunity typically lasts for years. There is nothing to suggest it will be any different in this particular case.

Widespread infection is not required for stopping the epidemic

The argument that 60% of the population must be infected and becomes immune before the infection spread is halted is based on an incorrect mathematical calculation. That calculation relies on two main assumptions:

1. The contact rate with others is the same for each person in a population

2. COVID-19 is a completely new virus, and therefore, there is no prior immunity. Any exposure to the virus will lead to an infection.

Recently, *Science*, one of the leading scientific journals, published an article that highlighted the absurdity underlying the calculation of the 60 percent threshold. The authors state an obvious fact: As far as contact rates are concerned, people do not interact identically with other people; some have more contacts than others. For example, a cashier at a supermarket and a taxi driver meet many more people than the average retiree. Since people with many social contacts are key factors in transmitting the virus, their immunity will contribute to stopping the spread of the virus more than people who have little contact with others. The former get infected sooner and become immune faster than people with low contact rate, so the spread of the virus reaches saturation at a level that is significantly lower than 60%. Again, the latter is founded on the false assumption of uniform social contacts for all members of a population.

The most significant evidence – decidedly refuting the need for 60% infection rate – is pre-immunity. For example, COVID-19 has several relatives (other coronaviruses) to which the population had been exposed, and such prior exposure can provide immunity to a significant segment of the population. Back in April, two of us wrote an article about the postulated nature of this immunity and the statistical evidence that pointed to its existence. We noted that in several closed communities that underwent testing, the infection rate was always capped at 20%, which statistically aligns with maximal infection rate in these communities rather than recurring coincidences. About a month later, a group of researchers published corroborating evidence in *Cell*, one of the most prestigious journals in the life sciences. About 60% of people in California who had never been exposed to COVID-19, had immune memory cells that recognized the virus and are therefore likely to provide immunity. Moreover, a study in Germany showed that such immunity could reach a level as high as 81% of the population. We assume that the situation in Israel is even better – for example, due to the age distribution (younger) and the number of children per household (higher). The above figure implies that less than 20% of the Israeli population is susceptible to an infection with the virus, while the vast majority is immune. A survey of cellular immunity is urgently needed to estimate the level of this type of immunity in Israel and in other countries.

This rate of pre-immunity to COVID-19 is also evident in the global rates of infection. The virus began infecting humans more than eight months ago, and the epidemic has already spread to most of the world. Yet in all countries, the infection rate remains below 20 percent of the general population. This limited rate of infection has remained unchanged regardless of social distancing measures (if any), such as quarantines, local or country-wide lockdown, mask-wearing, and so on. In Sweden, for example, the infection rate did not exceed 20% and the percentage of people who survived the epidemic exceeds 99.9% (!) of the population. Such is the case in Belgium as well, the country with the highest population mortality rate, where less than 20% were infected, and more than 99.9% of the population has survived the epidemic.

Assuming that approximately 80% of the Israeli population have some sort of cellular immunity – whether due to previous exposure to coronaviruses or for genetic or other reasons – we estimate that the epidemic will naturally fade away when 5 to 15 percent of the population is infected. The implications of these findings are of utmost importance. They call for immediate removal of most restrictions on the economy, immediate return to normal life of low-risk population while helping high-risk groups reduce the rate of social contacts (e.g., continuous monitoring of nursing homes and enabling diabetic teachers to work from home).

Trying to "mitigate" the pandemic will result in a heavy toll on human life

The third argument – removing restrictions will result in a higher mortality than a policy of lockdowns and restrictions – is also incorrect. A virus spreads in the population until enough people become infected and immune, or until a vaccine is found. Lockdowns and restrictions may only slow down its spread ("flatten the curve") but they do not lower the total number of infections or overall mortality. If there is a risk of overwhelming hospitals, there might be a need to slow the spread of the infection. Otherwise, flattening the curve can only be harmful since the infection returns once the restrictions are removed. Moreover, efficient protection of high-risk groups is possible only for a limited period of time: The longer the time, the harder it is to prevent their exposure to the virus. Therefore, paradoxically, it is precisely lockdowns and restrictions that slow the building of herd immunity, which in turn is needed to stop the epidemic and protect high-risk groups. In the long run, such policy can lead to excessive mortality. Another reason for an urgent policy change is that it seems that in Israel the fatality rate from the disease in the summer is several times lower than in the winter, even when correcting for statistical factors such as the increase in the number of tests.

The strongest evidence that a lockdown only suspends the infection, rather than abolish it, is that the infection resumes upon removal, as is happening now in Israel and elsewhere. In Sweden, on the other hand, there is no "second wave" because there was no lockdown. Thus, the policy of imposing and easing restrictions only prolongs the crisis, destroys the economy, and eventually leads to a larger number of victims. It may even continue for years as long as a vaccine is not available.

The alternative to lockdowns and restrictions must be seriously considered

It can be assumed that the handling of the COVID-19 crisis will be scrutinized – both in terms of health aspects, but also in light of public outrage over the state of the economy. So many people all over the world have lost their sources of income, livelihood, dignity and future. Poverty is a much more severe mortality risk factor than COVID-19, and it affects children as much as adults. One of the key questions that will surely be asked is whether the leadership in each country has ever seriously considered a worthy alternative to resolving the crisis, which will not cost so many human lives or destroy the economy. Countries such as Norway, Ireland, and Belgium have already declared that they will not impose further lockdowns as the obvious damage outweighs the doubtful benefit by a wide margin. To dispel economic uncertainty, the same must be declared immediately in Israel and other countries,

Israel has optimal conditions for coping with the pandemic, now

Now is the last chance for the leadership in Israel and other countries to declare that another lockdown will not be imposed, neither full nor partial. Israel has enormous advantages over Sweden and other countries in the context of the pandemic. The population is much younger on average (only about 11 percent of the population is older than 65). Israel has excellent medical services and logistical abilities to handle hospitalized patients in severe condition. The summer, which probably also has a positive effect on the virus spread and its fatality rate, is particularly long. In addition, there appears to be high natural immunity in the Middle East region, perhaps as a result of high exposure to common cold viruses (whereas Western European countries might have had "bald spots" of immunity as a result of deficient exposure to these viruses.) In light of its excellent opening conditions, Israel can now pursue a policy that protects the vulnerable populations, while striving to complete the immune layer needed to stop the virus spread, long before the 60 percent threshold. Thus, Israel can be at the end of the crisis in the coming months before winter arrives, thereby setting an example to the rest of the world.

Prof. Udi Qimron is the (elected) Head of Department of Clinical Microbiology and Immunology, Faculty of Medicine, Tel-Aviv University
Dr. Uri Gavish is a Physicist, an expert in Algorithm Analysis and a Bio-medical consultant
Prof. (Emeritus) Eyal Shahar is an Epidemiologist, University of Arizona
Prof. Michael Levitt is a Nobel Prize-winning (Chemistry, 2013) Structural Biology professor, Stanford University

The original article was published in *Ha'aretz* in Hebrew on July 20, 2020. The English text contains minor revisions.

United Health Professionals

PRESS RELEASE

PRESS RELEASE

October 29, 2020

Imprisoning again one's people is a crime against humanity that even the Nazis did not commit!

Despite the warnings of many professors of medicine, several experts and many medical or scientific collectives around the world (Mediziner und Wissenschaftler für Gesundheit, *Freiheit und Demokratie, e.V.*, Ärzte für Aufklärung, Laissons Les Médecins Prescrire, *Médicos Por La Verdad*, Belgium Beyond Covid, Artsen voor Waarheid, *Psicólogos Por La Verdad, Soignants Pour Une Politique Sanitaire Juste Et Proportionnée*, United Health Professionals, America's Frontline Doctors, Docs 4 Open Debate, World Doctors Alliance, *Médicos Por La Verdad Argentina, etc*), some governments as in France or Ireland want to repeat once again the serious error of the confinement (or the so called 'lockdown') which is neither more nor less than a **criminal incarceration and imprisonment of millions of people.** It is a **crime against humanity** that these governments must stop immediately, for several reasons:

1. The confinement is a heresy and an aberration created in 2020 that does not exist in medicine, epidemiology or public health and which is **not based on any scientific evidence of any effectiveness**. It is a **measure imported from China** and a real scam promoted by both the WHO and the Imperial College London, that is to say the same institutions involved in the swine flu global scandal. We must think by observing what happened in some countries:

- **Argentina** is the country that has practiced the longest confinement in the world (for 7 months!) and if we follow the reasoning of some advocates of confinement (often corrupted by the pharmaceutical industry), the result must be the control of the outbreak. Is that the case ? The answer is of course : no.
- **Sweden and Belarus** are the few countries that have not practiced the confinement at all, and if we follow the reasoning of the defenders of the confinement, we must have a massacre or an overwhelmed hospital system. Is that the case ? The answer is of course : no.

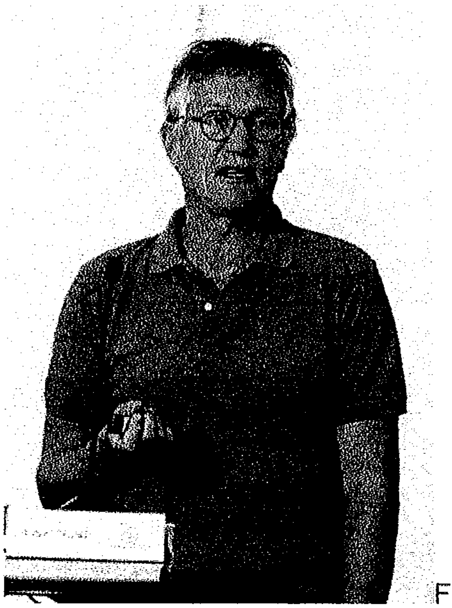
2. The lockdown, as **Professor Jean-François Toussaint** has called, is ***"a weapon of mass destruction"*** because of its consequences:

suicide of people as it was reported in China, development of psychiatric disorders, paralysis of the educational path of pupils and students at the university, negative impacts and dangers to animals, neglecting other diseases (especially chronic) and an increase in their mortality, domestic violence, economic losses, unemployment, major economic crisis (few people know that the economic crisis of 2007-2008 caused the suicide of at least 13,000 people in Europe and North America), serious consequences on agriculture, destabilization of countries and social peace, risk of wars. An editorial of ***Professor John Ioannidis*** *published in the European Journal Of Clinical Investigation has denounced,* ***from the beginning****, the harms of: non-*

evidence-based extreme measures, exaggerated information on the real danger of the virus and the fake news spread (even by major journals).

Tragedies occur every day: a teenage girl committed suicide in Great Britain because, for her, the lockdown lasted 300 years, 60,000 cancer patients could die in the UK because of a lack of treatment or diagnosis according to **Professor Karol Sikora**, 12,000 people could die **per day** by the end of the year as a result of hunger linked to COVID-19 measures (according to Oxfam), the number of cardiac arrests has doubled in some countries, companies go bankrupt, 305 million full-time jobs have been lost – affecting especially women and young people – according to the International Labour Organisation, etc. It should, also, be noted that the initial and primary cause of George Floyd's tragedy is **the lockdown**: if there was no lockdown, he would not have lost his job, he would have been on May 25 at work, he would not have been murdered, vandalism and fires of stores as well as the clashes with the police would not have happened, the chaos in the USA would have been avoided and George Floyd would still be alive among us today.

3. The Lockdown is a humiliation for a human being and a real dehumanization because **we confine animals and not human beings.** Here is the definition of the confinement, according to the Larousse dictionary : *"Situation of an animal population that is too large in a space that is too small and which, as a result, lacks oxygen, food or space"*.



For all these reasons, any government which not only practices lockdown but makes this mistake again **commits a real crime against humanity** and any doctor or any health professional who directly or indirectly encourages the confinement or masks for children is **a criminal in a white coat.** We don't manage an outbreak by imprisoning millions of people. It does not exist in public health and it is madness. **Dr. Anders Tegnell (pictured) said: *"The world went mad"*** with coronavirus lockdowns, which *"fly in the face of what is known about handling virus pandemics"*. **Professor Didier Raoult** said before yesterday:

"This country is experiencing a dramatic error...What are we going to suggest ? That everyone stay locked up all his life because there are viruses outside ? You're all crazy, you've become all nuts !".

We must remember points 13, 14, 17, 21 and 24 of the international alert message that the collective United Health Professionals (composed of more than 1,000 healthcare professionals from different countries in Europe, Africa, America and Asia) addressed to governments and citizens of countries around the world on August 26, 2020:

13. We say to the **police**: the citizens owe you a lot because you are every day the guarantors of their security and the respect of law and order. But this does not mean submitting blindly to unfair orders. It was this mistake that led to the second world war and the death of 50 million people. So, we tell you: enforce the law but not injustice and dictatorship, refuse to enforce these measures, refuse to verbalize your fellow citizens (when they are not wearing a mask for example), don't beat them, do not imprison them. Don't be the instruments of dictatorship. **Be on the side of the citizens** and follow the beautiful example of the American police officers who supported the citizens by kneeling with them.

We assure you that these measures have nothing to do with medicine or hygiene or the preservation of public health: it is dictatorship and madness.

14. We say to citizens: we must respect the law. But this does not mean blind submission to madness, injustice or dictatorship. It was this blind submission of citizens that led to the second world war with the death of 50 million people. **You were born free and you must live free**, therefore do not be afraid and if you are not sick, take off the masks, leave your house as you wish and without social distancing, but do it **peacefully** and without any violence. Professors Carl Heneghan and Tom Jefferson, epidemiologists with great expertise in evidence-based medicine, say: *"**There is no scientific evidence** to support the disastrous two-metre rule. Poor quality research is being used to justify a policy with enormous consequences for us all".*

17. We say that we must stop following blindly the WHO because it is not a learned society and is far from being independent, as we have seen. Asked about the reason for the decision to make 11 vaccines compulsory, a former health minister of a European country answered : *"It is a public health decision which in fact responds to **a global objective of the WHO which demands today** from all countries of the world to obtain 95% of children vaccinated for the necessary vaccines".*

We also recommend governments to choose well the experts who advise them and avoid those who have links with pharmaceutical companies;

An eminent professor in infectiology made this remark on certain experts of a European country:

*"**An eminent member of the High Council's Communicable Diseases Commission received 90,741 euros from the pharmaceutical industry**, including 16,563 euros from [the pharmaceutical laboratory which produces a competing molecule of hydroxychloroquine]. However, it is this High Council which made the famous decision of prohibiting hydroxychloroquine, except for those who will die...I do not see any trace in this decision of the respect of the procedure for managing conflicts of interest...If a member presents a major conflict of interest, he must leave the meeting and not*

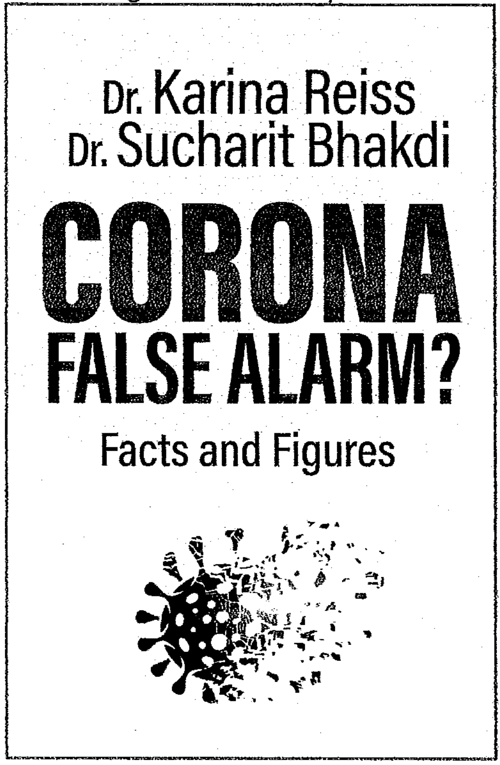
participate in the debates or in the writing of the decision...However, at the bottom of this decision, there is no mention of conflicts of interest or the number of members qualified who participated in the vote. It's a serious violation of the rules".

A former editor of the *New England Journal of Medicine* said :

"The medical profession is being bought by the pharmaceutical industry, *not only in terms of the practice of medicine, but also in terms of teaching and research. The academic institutions of this country are allowing themselves to be the paid agents of the pharmaceutical industry. I think it's disgraceful".*

This, of course, should not be generalized to everyone.

21. We say to governments: **EVERYTHING** must return **immediately to normal** *(including the reopening of hospital services, air transport, economy, schools and universities)* and **this global hostage-taking must stop** because you have known, with supporting evidence, that you as citizens, have been the victims of **the biggest health scam of the 21th century.** Professor Carl Heneghan said on August 23 that the public fear that is stopping the country returning to normal is unfounded, according to the Express. Professors Karina Reiss and Sucharit Bhakdi released a book in June called *"Corona : false alarm?"*. The mayor of a city in Europe declared: *"The atmosphere spread on [the subject of the coronavirus] is particularly heavy and becomes **suspicious**"*. Doctor Olivier Chailley has written a book called *"The virus of*



fear, how the whole world became crazy". Professor Sucharit Bhakdi *(he sent, also, a letter to Angela Merkel)* described the measures taken, including lockdown, as : *"grotesque, absurd and very dangerous…a horrible impact on the world economy…self-destruction and collective suicide…".*

An international and independent investigation must be opened and those responsible must be tried.

24. We invite health professionals **ALL AROUND THE WORLD** to be strong and courageous and to do their duty of telling the truth.

Among the signatories of the international alert message, **there are politicians like Doctor Martine Wonner, a deputy** from France and **Professor Jan Zaloudik, a senator** from the Czech Republic.

-Professor Peter Schönhöfer (physician, pharmacologist and European expert) said: *"It is an old marketing principle of pharmaceutical companies: if they want to sell their product, consumers must be afraid and see it as their salvation. So, we create a psychosis so that consumers crack up and rush to the vaccine in question".*

-Aristotle said: *"Slavery is never so successful as when the slave is convinced that it is for his good".*

-Professor Christian Perronne said : *"We are falling into a health dictatorship".* He also said : *"It is a frontal attack against the people and I think that the French people must revolt because there is no scientific justification".*

-Martin Luther King said : *"One has not only a legal but a moral responsibility to obey just laws. Conversely, one has a moral responsibility to disobey unjust laws. I agree with Saint Augustine that an unjust law is not at all a law".*

-Albert Einstein said : *"the world will not be destroyed by those who do evil, but by those who look at them without doing anything".*

The international alert message of the United Health Professionals collective addressed to governments and citizens of the whole world on August 26, 2020:

https://drive.google.com/file/d/1hghf8Bh3AIUi5HxrnPA8FZeQqo77e_xN/

-Facebook page : https://www.facebook.com/United-Health-Professionals-113530073772726

-YouTube channel : https://www.youtube.com/channel/UCI84pLXXDdyPqbhazvdvYUw/

-Twitter account : https://twitter.com/UnitedHealthPr2

-Email : join.unitedhealthprofessionals@gmail.com

The Vaccine Adverse Event Reporting System (VAERS) Results

Vaccine Manufacturer	Age	Events Reported	Percent (of 2,050)
JANSSEN	**30-39 years**	2	0.10%
	40-49 years	1	0.05%
	65+ years	13	0.63%
	Total	**16**	**0.78%**
MODERNA	**18-29 years**	5	0.24%
	30-39 years	5	0.24%
	40-49 years	19	0.93%
	50-59 years	63	3.07%
	60-64 years	58	2.83%
	65+ years	816	39.80%
	Unknown	50	2.44%
	Total	**1,016**	**49.56%**
PFIZER\BIONTECH	**1-2 years**	2	0.10%
	18-29 years	8	0.39%
	30-39 years	13	0.63%
	40-49 years	20	0.98%
	50-59 years	46	2.24%
	60-64 years	46	2.24%
	65+ years	768	37.46%
	Unknown	173	8.44%
	Total	**1,076**	**52.49%**
UNKNOWN MANUFACTURER	**60-64 years**	1	0.05%
	65+ years	4	0.20%
	Unknown	2	0.10%
	Total	**7**	**0.34%**
Total		**2,115**	**103.17%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more then 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 3/19/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Values of Event Category field vary in their availability over time due to changes in the reporting form. The "Emergency Room/Office Visit" value was avaliable only for events reported using the VAERS-1 form, active 07/01/1990 to 06/29/2017. The "Congenital Anomaly/Birth Defect", "Emergency Room", and "Office Visit" values are available only for events reported using the VAERS 2.0 form, active 06/30/2017 to present. These changes must be considered when evaluating count of events for these categories.

For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Mar 29, 2021 11:57:43 AM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/19/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Mar 29, 2021 11:57:43 AM

Query Criteria:

Event Category:	Death
Vaccine Products:	COVID19 VACCINE (COVID19)
Group By:	Vaccine Manufacturer; Age
Show Totals:	True
Show Zero Values:	False

The Vaccine Adverse Event Reporting System (VAERS) Results

Vaccine Manufacturer	Age	Events Reported	Percent (of 1,318)
JANSSEN	**30-39 years**	1	0.08%
	40-49 years	3	0.23%
	50-59 years	2	0.15%
	60-64 years	2	0.15%
	Total	**8**	**0.61%**
MODERNA	**18-29 years**	47	3.57%
	30-39 years	76	5.77%
	40-49 years	93	7.06%
	50-59 years	95	7.21%
	60-64 years	43	3.26%
	65+ years	270	20.49%
	Unknown	19	1.44%
	Total	**643**	**48.79%**
PFIZER\BIONTECH	**6-17 years**	3	0.23%
	18-29 years	33	2.50%
	30-39 years	95	7.21%
	40-49 years	117	8.88%
	50-59 years	105	7.97%
	60-64 years	40	3.03%
	65+ years	298	22.61%
	Unknown	26	1.97%
	Total	**717**	**54.40%**
UNKNOWN MANUFACTURER	**65+ years**	1	0.08%
	Total	**1**	**0.08%**
Total		**1,369**	**103.87%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more then 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 3/19/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Values of Event Category field vary in their availability over time due to changes in the reporting form. The "Emergency Room/Office Visit" value was avaliable only for events reported using the VAERS-1 form, active 07/01/1990 to 06/29/2017. The "Congenital Anomaly/Birth Defect", "Emergency Room", and "Office Visit" values are available only for events reported using the VAERS 2.0 form, active 06/30/2017 to present. These changes must be considered when evaluating count of events for these categories.

For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Mar 29, 2021 12:00:54 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/19/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Mar 29, 2021 12:00:54 PM

Query Criteria:

Event Category: Life Threatening
Vaccine Products: COVID19 VACCINE (COVID19)
Group By: Vaccine Manufacturer; Age
Show Totals: True
Show Zero Values: False

The Vaccine Adverse Event Reporting System (VAERS) Results

Vaccine Manufacturer	Age	Events Reported	Percent (of 4,450)
JANSSEN	**1-2 years**	1	0.02%
	18-29 years	2	0.04%
	30-39 years	8	0.18%
	40-49 years	4	0.09%
	50-59 years	10	0.22%
	60-64 years	7	0.16%
	65+ years	11	0.25%
	Unknown	1	0.02%
	Total	**44**	**0.99%**
MODERNA	**6-17 years**	1	0.02%
	18-29 years	124	2.79%
	30-39 years	152	3.42%
	40-49 years	205	4.61%
	50-59 years	256	5.75%
	60-64 years	129	2.90%
	65+ years	1,183	26.58%
	Unknown	132	2.97%
	Total	**2,182**	**49.03%**
PFIZER\BIONTECH	**1-2 years**	1	0.02%
	6-17 years	3	0.07%
	18-29 years	118	2.65%
	30-39 years	230	5.17%
	40-49 years	219	4.92%
	50-59 years	242	5.44%
	60-64 years	128	2.88%
	65+ years	1,247	28.02%
	Unknown	169	3.80%
	Total	**2,357**	**52.97%**
UNKNOWN MANUFACTURER	**40-49 years**	2	0.04%
	50-59 years	1	0.02%
	60-64 years	1	0.02%
	65+ years	3	0.07%
	Total	**7**	**0.16%**
Total		**4,590**	**103.15%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

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For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Mar 29, 2021 12:03:53 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/19/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Mar 29, 2021 12:03:53 PM

Query Criteria:

Event Category:	Hospitalized
Vaccine Products:	COVID19 VACCINE (COVID19)
Group By:	Vaccine Manufacturer; Age
Show Totals:	True
Show Zero Values:	False

The Vaccine Adverse Event Reporting System (VAERS) Results

Vaccine Manufacturer	Age	Events Reported	Percent (of 44,606)
JANSSEN	**1-2 years**	1	0.00%
	6-17 years	5	0.01%
	18-29 years	178	0.40%
	30-39 years	215	0.48%
	40-49 years	148	0.33%
	50-59 years	303	0.68%
	60-64 years	101	0.23%
	65+ years	148	0.33%
	Unknown	10	0.02%
	Total	**1,109**	**2.49%**
MODERNA	**< 6 months**	2	0.00%
	6-11 months	2	0.00%
	1-2 years	19	0.04%
	6-17 years	152	0.34%
	18-29 years	2,207	4.95%
	30-39 years	3,746	8.40%
	40-49 years	3,633	8.14%
	50-59 years	3,429	7.69%
	60-64 years	1,374	3.08%
	65+ years	4,190	9.39%
	Unknown	808	1.81%
	Total	**19,562**	**43.86%**
PFIZER\BIONTECH	**< 6 months**	2	0.00%
	6-11 months	4	0.01%
	1-2 years	12	0.03%
	6-17 years	23	0.05%
	18-29 years	2,628	5.89%
	30-39 years	4,844	10.86%
	40-49 years	4,531	10.16%
	50-59 years	3,802	8.52%
	60-64 years	1,418	3.18%
	65+ years	4,254	9.54%
	Unknown	2,779	6.23%
	Total	**24,297**	**54.47%**
UNKNOWN MANUFACTURER	**18-29 years**	2	0.00%
	40-49 years	4	0.01%
	50-59 years	2	0.00%
	60-64 years	2	0.00%
	65+ years	7	0.02%
	Unknown	13	0.03%
	Total	**30**	**0.07%**
Total		**44,998**	**100.88%**

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Notes:

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Data contains VAERS reports processed as of 3/19/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Mar 29, 2021 12:05:29 PM

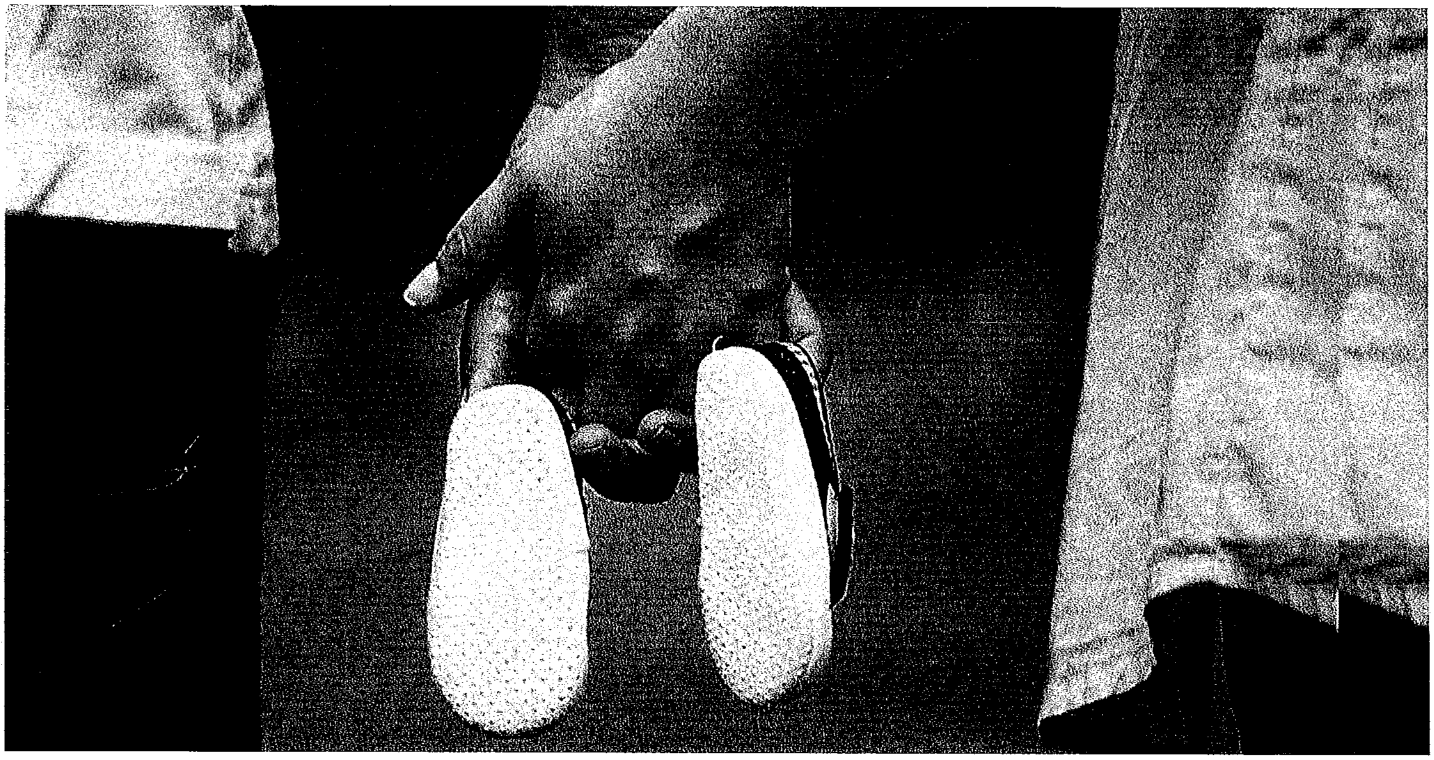
Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/19/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Mar 29, 2021 12:05:29 PM

Query Criteria:

Vaccine Products:	COVID19 VACCINE (COVID19)
Group By:	Vaccine Manufacturer; Age
Show Totals:	True
Show Zero Values:	False

EN SÓLO 6 SEMANAS HUBO UN AUMENTO DE UN 366% DE PÉRDIDAS DE BEBES POR NACER EN MADRES QUE RECIBIERON LA INYECCIÓN C 0 V iD



La última actualización sobre la cantidad de niños no nacidos y recién nacidos que pierden la vida como resultado de que las madres recibieron una de las vacunas C0 V ¡D en el Reino Unido.

En el informe de EudraVigilance lanzado por la Agencia Europea de Medicamentos hasta el 13 de marzo de 2021 enumeraba **3.964 muertes y 162.610 lesiones** luego de inyecciones de tres tipos de "vacunas" experimentales contra el C0 V ¡D

El Gobierno ha publicado informes semanales sobre reacciones adversas a las vacunas experimentales **C0 V ¡D**, el primero de los cuales cubría los datos ingresados en el Sistema de Tarjeta Amarilla MHRA desde el 9 de diciembre de 2020 hasta el 24 de enero de 2021. Su último informe (*encuéntrelo aquí*), que es el séptimo en publicado, cubre los datos ingresados en el Esquema de Tarjeta Amarilla de la MHRA desde el **9 de diciembre de 2020 hasta el 7 de marzo de 2021**.

Solo seis semanas separan el primer y el séptimo informe, y el sorprendente aumento en el número de mujeres que pierden a su hijo por nacer y al recién nacido en ese tiempo debido a la vacuna Pfizer o AstraZeneca contra **C0 V ¡D** .

Este fue el consejo del propio gobierno de UK sobre la aprobación de emergencia de la vacuna Pfizer / BioNTech:

Embarazo

No hay datos o son limitados sobre el uso de la vacuna de ARNm de **C0 V ¡D** BNT162b2. **No se han completado los** estudios de toxicidad reproductiva en animales . **No se recomienda la vacuna** COVID-19 mRNA **BNT162b2 (BioNTech & Pfizer) durante el embarazo.** Para las mujeres en edad fértil, se debe excluir el embarazo antes de la vacunación. Además, se debe advertir a las mujeres en edad fértil que **eviten el embarazo durante al menos 2 meses después de su segunda dosis**.

Los consejos de los gobiernos también incluían comentarios sobre la lactancia materna y la fertilidad, que eran los siguientes:

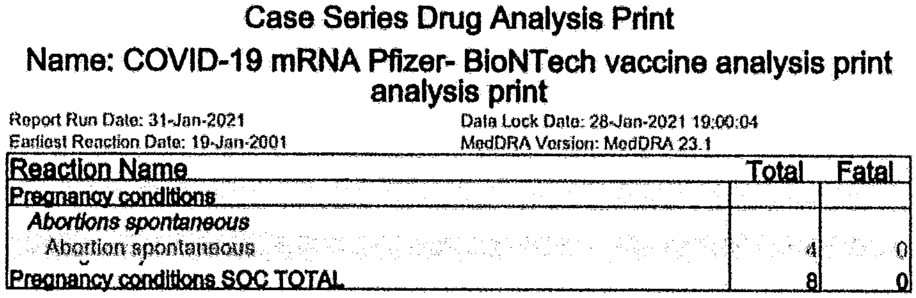
Lactancia

Se desconoce si la vacuna de ARNm de **C0 V ¡D** BNT162b2 se excreta en la leche materna.

No se puede excluir un riesgo para los recién nacidos / bebés. La vacuna de ARNm de **C0 V ¡D** BNT162b2 no debe usarse durante la lactancia.

Fertilidad Se **desconoce** si la vacuna de ARNm de **C0 V ¡D** BNT162b2 tiene un **impacto en la fertilidad ".**

Es debido a este consejo publicado por el gobierno del Reino Unido que sorprende ver en el primer informe publicado de reacciones adversas a las vacunas **C0 V ¡D**, utilizando datos ingresados en el Esquema de Tarjeta Amarilla MHRA hasta el 24 de enero de 2021, un total de 4 las mujeres habían sufrido un aborto espontáneo como resultado de recibir la vacuna Pfizer / BioNTech.



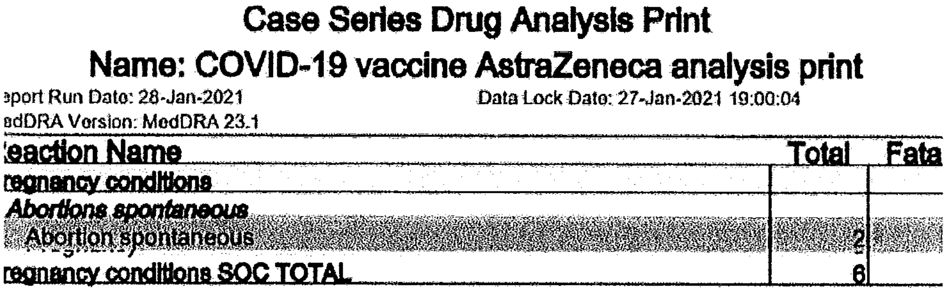
Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print analysis print

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001
Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	4	0
Pregnancy conditions SOC TOTAL	8	0

Así como un total de 2 mujeres que perdieron a su bebepor nacer como resultado de la vacuna Oxford / AstraZeneca.



Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

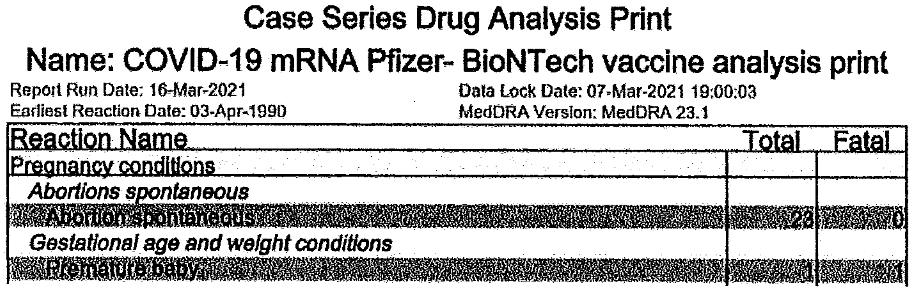
eport Run Date: 28-Jan-2021 Data Lock Date: 27-Jan-2021 19:00:04
edDRA Version: MedDRA 23.1

eaction Name	Total	Fata
regnancy conditions		
Abortions spontaneous		
Abortion spontaneous	2	
regnancy conditions SOC TOTAL	6	

No se entiende por qué a estas mujeres se les dio una de las vacunas **C0 V ¡D** en contra del propio consejo del gobierno. Pero lo realmente impactante es cuánto ha aumentado este número en las 6 semanas que se han desarrollado desde entonces.

Según el séptimo informe publicado por el gobierno del Reino Unido sobre reacciones adversas a las vacunas **C0 V ¡D**, utilizando los datos ingresados en el MHRA Yellow Card Scheme hasta el 7 de marzo de 2021, **ha habido un aumento del 475%** desde el 24 de enero en el número de mujeres. que han perdido a su hijo por nacer después de recibir la vacuna Pfizer, lo que eleva el total a 23.

Ahora también hay un informe de un bebé prematuro que lamentablemente muere después de que la madre recibió la vacuna Pfizer.



Case Series Drug Analysis Print

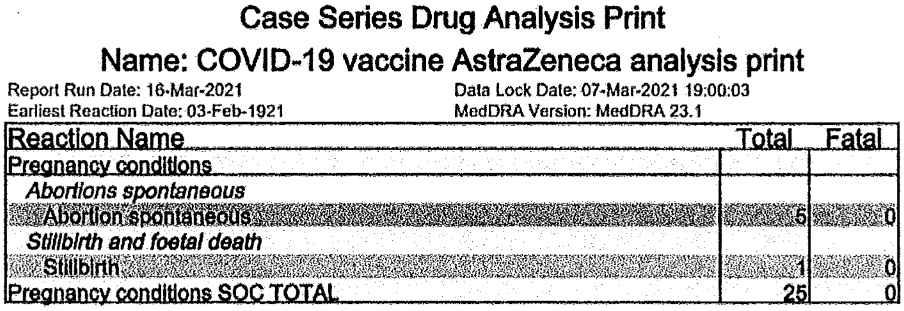
Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 03-Apr-1990 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	23	0
Gestational age and weight conditions		
Premature baby	1	1

La inyección de AstraZeneca también ha causado dolor innecesario a las mujeres embarazadas. A partir del 7 de marzo ha habido un aumento del **150%** desde el 24 de enero en el número de mujeres que sufrieron **aborto espontáneo,** con lo que el total asciende a 5.

Trágicamente, también se informó un nacimiento muerto al Sistema de Tarjeta Amarilla de la MHRA después de que la madre recibió la vacuna AstraZeneca, pero sorprendentemente esto no ha sido etiquetado como una fatalidad.



Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	5	0
Stillbirth and foetal death		
Stillbirth	1	0
Pregnancy conditions SOC TOTAL	25	0

La pregunta es ¿por qué estamos viendo estos números cuando el propio consejo del gobierno fue que las mujeres embarazadas no deberían vacunarse? ¿**Y porque en Argentina se esta experimentando con mujeres embarazadas cuando se sabe que esto está ocurriendo**?

Recientemente el de UK gobierno actualizó su consejo original a lo siguiente:

> 4.6 Fertilidad, embarazo y lactancia
>
> **Embarazo**
>
> Existe una experiencia limitada con el uso de la vacuna de ARNm de **C0 V ¡D** BNT162b2 en mujeres embarazadas.
>
> Los estudios en animales no indican efectos dañinos directos o indirectos con respecto al embarazo, desarrollo embrionario / fetal, parto o desarrollo posnatal. La administración de la vacuna de ARNm de COVID-19 BNT162b2 durante el embarazo **solo debe considerarse** cuando los **beneficios potenciales** superan cualquier **riesgo potencial** para la **madre** y el **feto.**

El consentimiento informado es importante, no creemos que estas mujeres hayan sido debidamente informadas y ahora tendrán que sufrir el dolor eterno de perder a su hijo por nacer o recién nacido.

EudraVigilance

EudraVigilance fue lanzado por la Agencia Europea de Medicamentos en 2012 para brindar acceso público a informes de sospechas de efectos secundarios. Estos informes se envían electrónicamente a EudraVigilance por las autoridades reguladoras de medicamentos nacionales y por las empresas farmacéuticas que poseen autorizaciones de comercialización (licencias) para los medicamentos.

En el informe de EudraVigilance lanzado por la Agencia Europea de Medicamentos hasta el 13 de marzo de 2021 enumeraba 3.964 muertes y 162.610 lesiones luego de inyecciones de tres tipos de "vacunas" experimentales contra el C0 V ¡D

- Vacuna ARNm COVID-19 Moderna (CX-024414),
- Vacuna ARNm COVID-19 Pfizer-Biontech (TOZINAMERAN) y
- Vacuna COVID-19 Astrazeneca (CHADOX1 NCOV-19).

Reacciones totales para la vacuna de ARNm experimental ARNm -1273 (CX-024414) de Moderna:

973 muertos y 5.939 heridos a 13/03/2021

- 330 Trastornos de la sangre y del sistema linfático, incl. **9 muertos**
- 501 Trastornos cardíacos incl. **96 muertes**
- 1 Trastornos congénitos, familiares y genéticos
- 116 Trastornos del oído y del laberinto
- 6 Trastornos endocrinos
- 181 Trastornos oculares incl. **2 muertes**
- 1.283 Trastornos gastrointestinales incl. **40 muertes**
- 4.198 Trastornos generales y alteraciones en el lugar de administración, incl. **393 muertes**
- 21 Trastornos hepatobiliares
- 219 Trastornos del sistema inmunológico, incl. **1 muerte**
- 515 Infecciones e infestaciones incl. **57 muertes**
- 236 Lesiones, intoxicaciones y complicaciones de procedimientos, incl. **16 muertes**
- 411 Investigaciones incl. **36 muertes**
- 165 Trastornos del metabolismo y de la nutrición incl. **18 muertos**
- 1.727 Trastornos musculoesqueléticos y del tejido conjuntivo, incl **. 23 muertos**
- 12 Neoplasias benignas, malignas y no especificadas (incluidos quistes y pólipos) incl. **3 muertes**
- 2.324 Trastornos del sistema nervioso, incl. **111 muertes**
- 15 Embarazo, puerperio y afecciones perinatales
- 4 Problemas con el producto
- 271 Trastornos psiquiátricos incl. **14 muertes**
- 93 Trastornos renales y urinarios incl. **10 muertes**
- 34 Trastornos del aparato reproductor y de las mamas, incl. **1 muerte**
- 817 Trastornos respiratorios, torácicos y mediastínicos, incl. **93 muertes**

- 740 Trastornos de la piel y del tejido subcutáneo, incl. **11 muertes**
- 48 Circunstancias sociales incl **. 3 muertes**
- 40 Procedimientos médicos y quirúrgicos incl. **4 muertos**
- 368 Trastornos vasculares incl. **32 muertes**

Reacciones totales para la vacuna experimental AZD1222 (CHADOX1 NCOV-19) de Oxford / AstraZeneca:

451 muertes y 54.571 lesiones a 13/03/2021

- 1.180 Trastornos de la sangre y del sistema linfático, incl. **11 muertes**
- 2.080 Trastornos cardíacos incl. **63 muertes**
- 17 Trastornos congénitos, familiares y genéticos
- 1.237 Trastornos del oído y del laberinto
- 41 Trastornos endocrinos
- 1.977 Trastornos oculares incl. 1 **muerte**
- 17.491 Trastornos gastrointestinales incl. **15 muertes**
- 42,367 Trastornos generales y alteraciones en el lugar de administración, incl. **198 muertes**
- 32 Trastornos hepatobiliares incl. **1 muerte**
- 578 Trastornos del sistema inmunológico
- 3.340 Infecciones e infestaciones incl. **46 muertes**
- 853 Lesiones, intoxicaciones y complicaciones de procedimientos, incl. **2 muertes**
- 2.384 Investigaciones incl. **3 muertes**
- 2.676 Trastornos del metabolismo y de la nutrición incl. **5 muertes**
- 22.858 Trastornos musculoesqueléticos y del tejido conjuntivo incl. **4 muertos**
- 19 Neoplasias benignas, malignas y no especificadas (incluidos quistes y pólipos) incl. **2 muertes**
- 32.490 Trastornos del sistema nervioso, incl. **41 muertes**
- 22 Embarazo, puerperio y afecciones perinatales
- 11 Problemas con el producto
- 3.105 Trastornos psiquiátricos incl. **3 muertes**
- 560 Trastornos renales y urinarios incl. **4 muertos**
- 266 Trastornos del aparato reproductor y de la mama

403

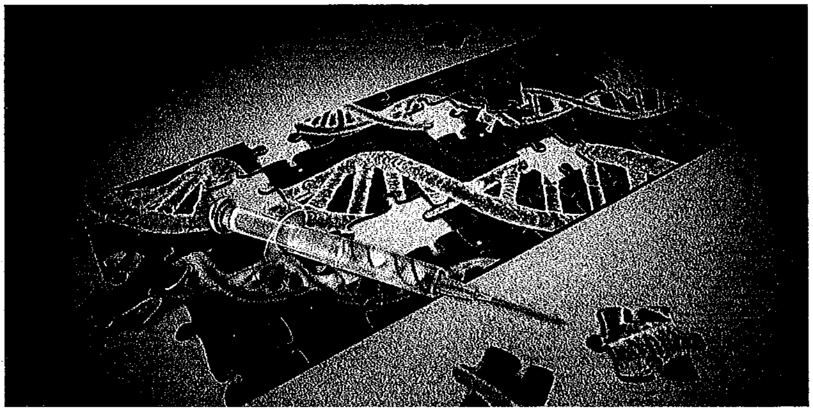
- 4.293 Trastornos respiratorios, torácicos y mediastínicos incl. **33 muertes**
- 6.815 Trastornos de la piel y del tejido subcutáneo, incl. **2 muertes**
- 99 Circunstancias sociales incl. **2 muertes**
- 138 Procedimientos médicos y quirúrgicos incl. **4 muertos**
- 1.656 Trastornos vasculares incl. **11 muertes**

Esta es información pública financiada por la Agencia Europea de Medicamentos (EMA), pero está siendo censurada por los medios corporativos.

Pfizer experimentará con embarazadas en la Argentina

Pfizer experimentará con embarazadas en la Argentina. La tasa actual es que 1 de cada 250 personas que reciben una dosis de la inyección sufren una reacción adversa.

CienciaySaludNatural.com



Quieren imponer la inyección de terapia génica en niños

Se esta experimentado con inyección de terapia génica en niños cuando la tasa de supervivencia de C0 V ¡D 9 es del 99,997, esto es la abominación de la desolación.

CienciaySaludNatural.com

405

I've attached the slides of the keynote that I held yesterday at the Vaccine Summit in Ohio ("Why should current Covid-19 vaccines not be used for mass vaccination during a pandemic?"). Please do have a look at them. The bottom-line is that I don't see how mass vaccination campaigns would not lead to a disastrous aggravation of the Covid-19 pandemic. However, no one else seems to realize; instead, vaccinologists, clinicians and scientists are merely focusing on the (positive) _short-term_ results and impact at an _individual_ level. Nobody seems to be looking at the consequences and risk at a human population level (which, according to my understanding, will become manifest quite soon).

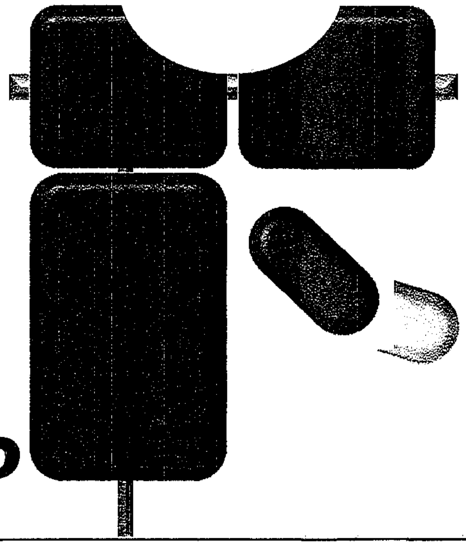
Why is nobody worried about 'immune escape' whereas Covid-19 has already escaped people's innate immunity as reflected by multiple emerging, much more infectious, viral variants (most likely due to the global implementation of infection prevention measures)? Vaccine deployment in the ongoing mass immunization campaigns are highly likely to further enhance (adaptive) immune escape as none of the current vaccines will prevent replication/ transmission of viral variants. The more we use these vaccines for immunizing people in the midst of a pandemic, the more infectious the virus will become. With increasing infectiousness comes an increased likelihood of viral resistance to the vaccines. It's not exactly rocket science, it's a basic principle taught in a student's first vaccinology class: One shouldn't use a prophylactic vaccine in populations exposed to high infectious pressure (which is now certainly the case as multiple highly infectious variants are currently circulating in many parts of the world). To fully escape selective immune pressure exerted by vaccinal antibodies, Covid-19, *a highly mutable* virus, only needs to add another few mutations in its receptor-binding domain ...

I am beyond worried about the disastrous impact this would have on our human 'race'. Not only would people lose vaccine-mediated protection but also their precious, variant-nonspecific (!), innate immunity will be gone (this is because vaccinal antibodies outcompete natural antibodies for binding to Covid-19, even when their affinity for the viral variant is relatively low).

I've alerted all responsible health and regulatory authorities, including WHO, CDC, FDA etc. and have asked to consider my concern and to immediately open the discussion about the disastrous consequences any further immune escape of Covid-19 would have.

I know, of course, that current mass vaccination campaigns enjoy vigorous and world-wide support from a multitude of different parties/ stakeholders. However, unless I am proven wrong, this cannot be an excuse for ignoring that mankind may currently be transforming a quite harmless virus into an uncontrollable monster. I've never been that serious about a statement I made.

Why should current Covid-19 vaccines not be used for mass accination during a pandemic?



Vaccines Summit Ohio 2021
March 1-3, 2021
Ohio, USA

G. Vanden Bossche, DVM, PhD
Independent Vaccine Research Consultant

Prophylactic vaccines are for use in…a conventional prophylactic setting, NOT in a pandemic setting

- Prophylactic vaccines should be administered before infectious exposure to:
    - ensure full-fledged protection
    - prevent exacerbation of disease (cfr. Ebola – ring vaccination)
    - *prevent immune escape* and hence, enhanced infectiousness or even, resistance to the vaccine

- Several cases of severe disease due to highly infectious variants have already occurred in young people
- Several cases of fully Covid-19 vaccinated people shedding highly infectious variants have already been reported (some of which have even developed mild symptoms)

Aren't these cases compelling enough to demonstrate how easily Covid-19 viruses can escape host immunity?

General Rule: Virus replication on background of suboptimal immune response enables immune escape of highly mutable viruses.

Current Covid-19 vaccine technologies

- All of them are targeted at inducing specific Abs to S-protein (S1- RBD), so none of them prevents viral replication if Abs are too low in concentration or *affinity*
- They cannot control replication of more infectious CoV variants and may even drive immune escape (e.g., when fully vaccinated subjects are exposed to viral variants)

- Are they safe?
  - yes, at the level of the individual
  - absolutely not, for human populations exposed to Covid-19 pandemic

- Are they efficacious for protecting against disease?
  - yes, at the level of the individual
  - absolutely not, for human populations exposed to Covid-19 pandemic

Abs: Antibodies

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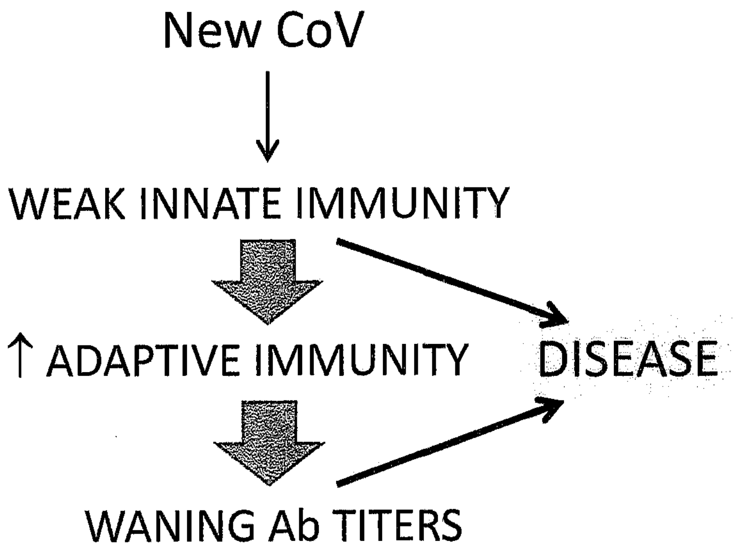
;aps in our understanding of the natural course of viral pandemics

NACs*:

- Ag-nonspecific killing via natural Abs (NABs) and NK cells provide natural immunity



New CoV

WEAK INNATE IMMUNITY

↑ ADAPTIVE IMMUNITY

WANING Ab TITERS

DISEASE

nonNACs**:

- Contract disease because of weak innate immunity
- Ag-specific killing (neutralization) via 'adaptive' Abs → protection
- Susceptible to disease when Ab titers wane

Q: - Why does natural (i.e;, w/o human intervention) viral pandemic comprise 3 waves?

- **Why does 2nd wave typically hit younger people**?

- Why / how does the virus re-emerge to become seasonal?

Ag: Antigen; Abs: Antibodies

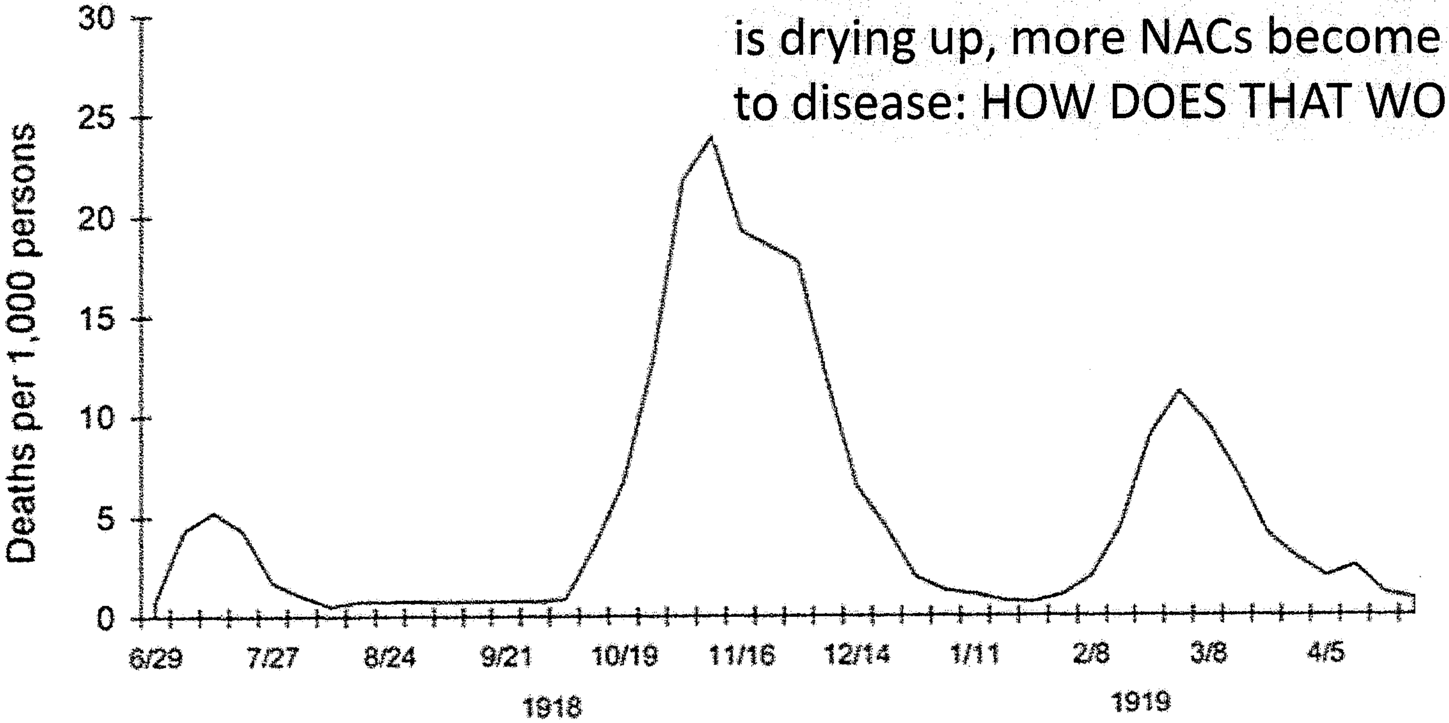
*NACs: Natural asymptomatic carriers ; refers to subjects who do not develop any clinical symptoms at all, or develop at most mild disease (involving upper respiratory airways only), after PRIMARY CoV infection

**nonNACs: Relates to subjects who develop severe Covid-19 symptoms after PRIMARY infection

The current COVID-19 pandemic is often compared to the 1918 H1N1 influenza pandemic

For example, the 1889-92 influenza outbreak had three distinct waves, which differed in their virulence. The second wave was much more severe, particularly in younger adults.

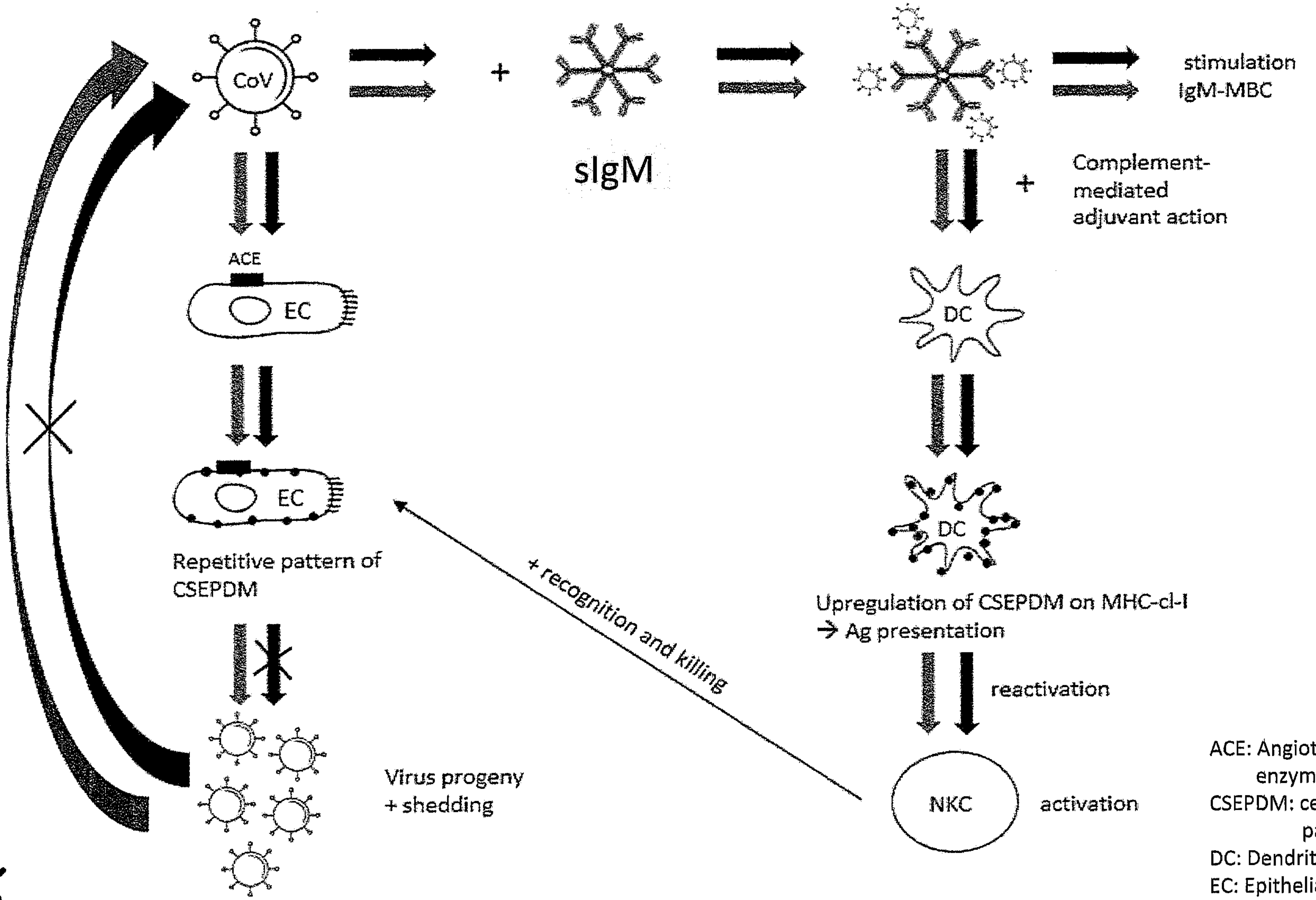
As major source of viral spread (nonNACs) is drying up, more NACs become susceptible to disease: HOW DOES THAT WORK?



Three waves of death: weekly combined influenza and pneumonia mortality, United Kingdom, 1918–1919. The waves were broadly the same globally during the pandemic.

The current COVID-19 pandemic is often compared to the 1918 H1N1 influenza pandemic, which had three distinct waves over the course of a year. The proportion of influenza patients who were severely ill or died was much higher in the last two waves compared to the first.

Abrogation of viral infection in NACs (after short-lived virus replication) is mediated by innate immunity


CoV
+
sIgM
stimulation
IgM-MBC
+
Complement-
mediated
adjuvant action
ACE
EC
EC
Repetitive pattern of
CSEPDM
DC
DC
Upregulation of CSEPDM on MHC-cl-I
→ Ag presentation
reactivation
+ recognition and killing
Virus progeny
+ shedding
NKC
activation

ACE: Angiotensin –converting enzyme
CSEPDM: cell surface-expressed pathogen-derived motif
DC: Dendritic cell
EC: Epithelial cell
MBC: Memory B cell
NKC: Natural Killer cell

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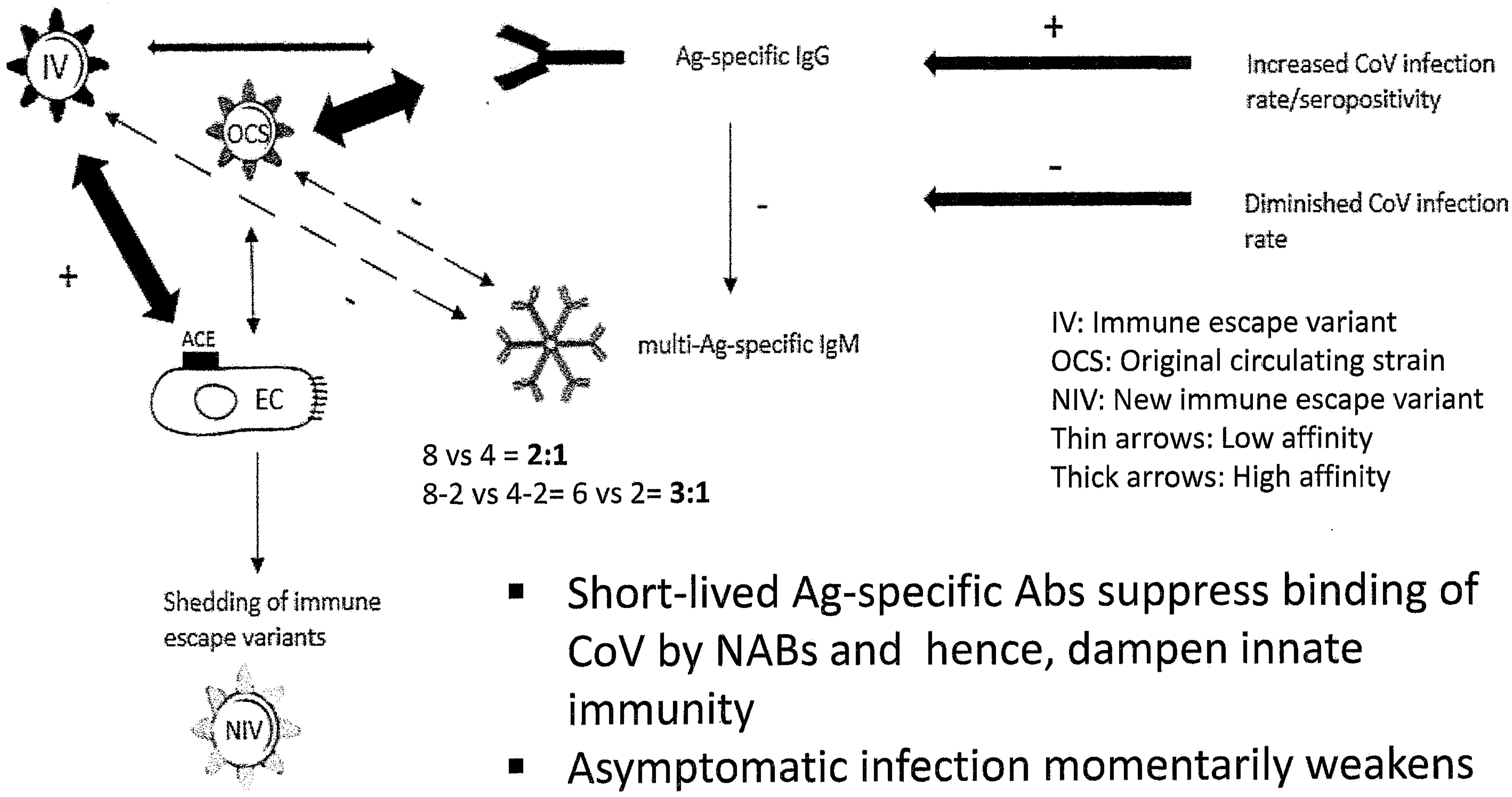
Abrogation of viral infection at an early stage of infection is the virus' secret weapon to ensure its own perpetuation


IV
OCS
Ag-specific IgG
+
Increased CoV infection rate/seropositivity
-
Diminished CoV infection rate
+
-
-
-
ACE
EC
multi-Ag-specific IgM
Shedding of immune escape variants
NIV

8 vs 4 = **2:1**
8-2 vs 4-2= 6 vs 2= **3:1**

IV: Immune escape variant
OCS: Original circulating strain
NIV: New immune escape variant
Thin arrows: Low affinity
Thick arrows: High affinity

- Short-lived Ag-specific Abs suppress binding of CoV by NABs and hence, dampen innate immunity
- Asymptomatic infection momentarily weakens innate immunity without providing protective adaptive immunity → ↑ susceptibility to disease

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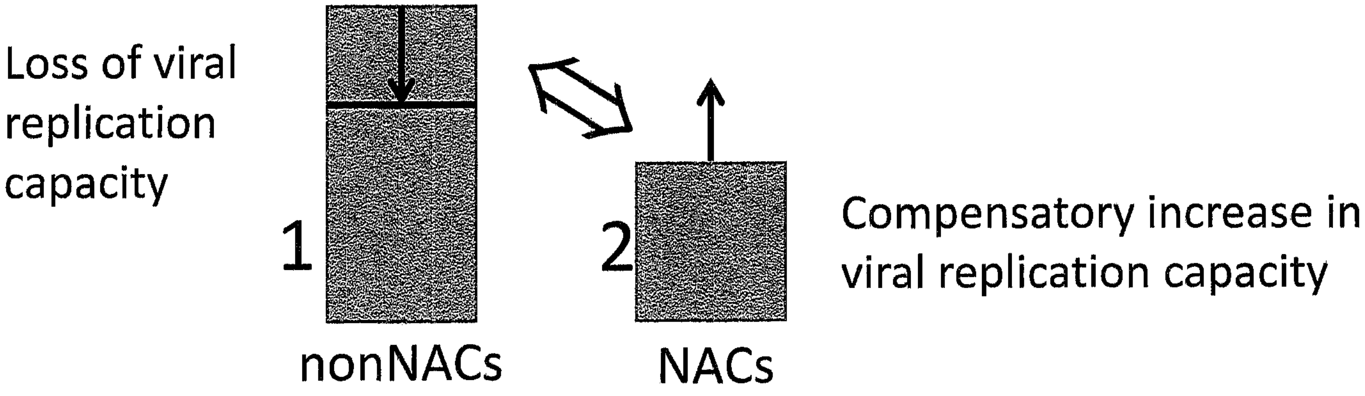
Increasing CoV infection rates promote enhancement of innate immune suppression in NACs (→more susceptible to disease)



Loss of viral replication capacity

1

nonNACs

2

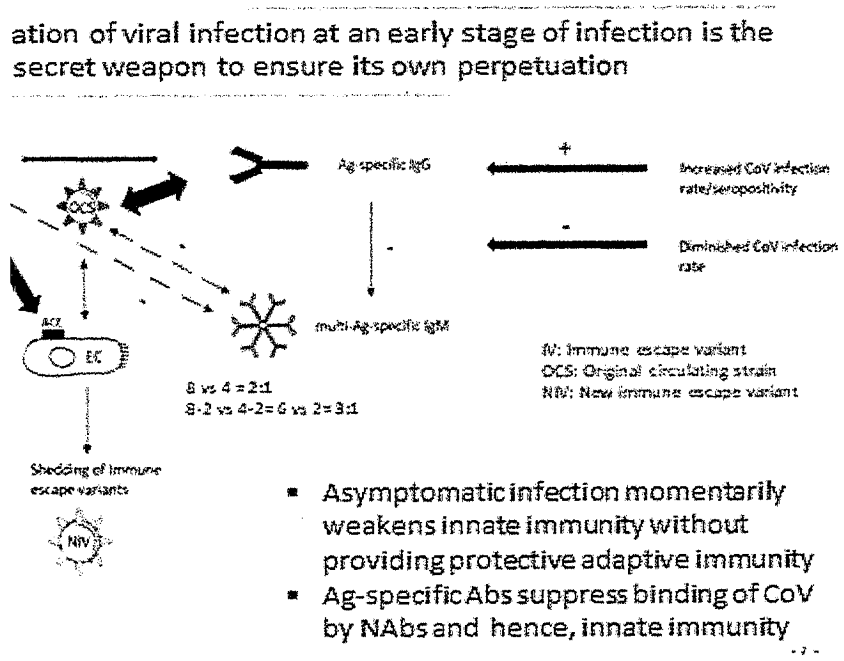
NACs

Compensatory increase in viral replication capacity

↑
susceptibility rate in NACs suffices to compensate for long enough....
until Ag-spec. Ab titers in nonNACs drop ⇒ virus can replenish replication capacity

414

Containment measures and vaccination of NACs jeopardize capacity for viral replication



ation of viral infection at an early stage of infection is the secret weapon to ensure its own perpetuation

Ag-specific IgG
+
Increased CoV infection rate/seropositivity
-
Diminished CoV infection rate
OCS
ACE
EC
multi-Ag-specific IgM
8 vs 4 = 2:1
8-2 vs 4-2= 6 vs 2= 3:1
IV: Immune escape variant
OCS: Original circulating strain
NIV: New immune escape variant
Shedding of immune escape variants
NIV

- Asymptomatic infection momentarily weakens innate immunity without providing protective adaptive immunity
- Ag-specific Abs suppress binding of CoV by NAbs and hence, innate immunity

- 7 -

Abrogation of viral infection at an early stage of infection is the virus' secret weapon to ensure its own perpetuation **while leaving the door open for increasing its infectiousness when infection rates drop**

Since virus replication in NACs is under control of (innate) immune system, the virus can compensate for loss of replication/transmission capacity by enhancing infectiousness through selective immune escape

⇩

↑**viral infectiousness in NACs** suffices to compensate for long enough….
until Ag-spec. Ab titers in nonNACs drop

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But what if these Ab titers don't drop??

- Steady S-spec. Ab titers (VACCINATION!) in nonNACs will result in further increase in viral infectiousness in NACs…. until 'return' on escape mutations in nonNACs becomes relatively more profitable for the virus

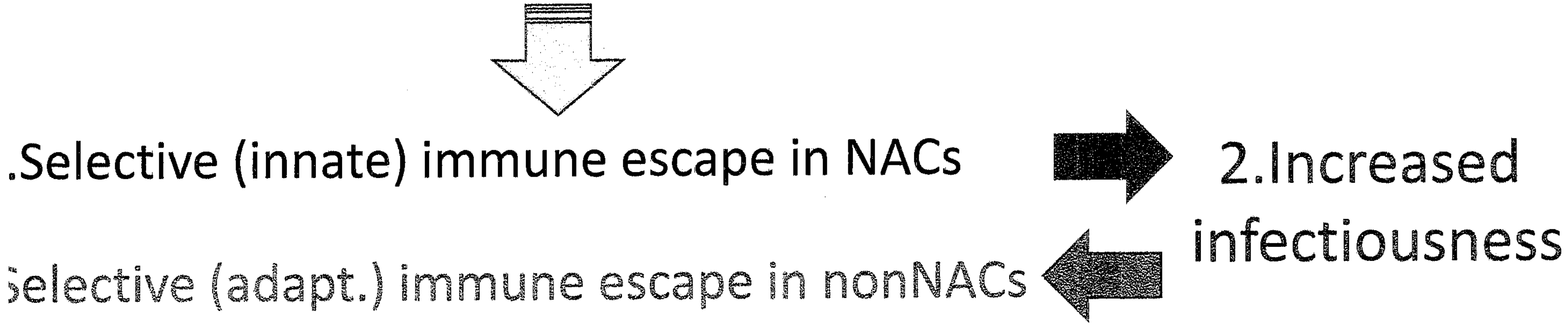
↓

- RBD-specific escape mutations enable virus to rebuild sufficient capacity for viral replication in nonNACs.
  The resulting immune escape variants are now resistant to the vaccine.

9/16

Increasing infection/ seropositivity rates in NACs and nonNACs promote immune escape

- Enhanced infection rates lead to increased rates of transient seropositivity in NACs; seropositivity suppresses innate immunity because Ag-specific Abs outcompete NABs for binding to CoV and prevent training of innate immune system



.Selective (innate) immune escape in NACs

2.Increased infectiousness

elective (adapt.) immune escape in nonNACs

Strange observations during ongoing Covid-19 pandemic..

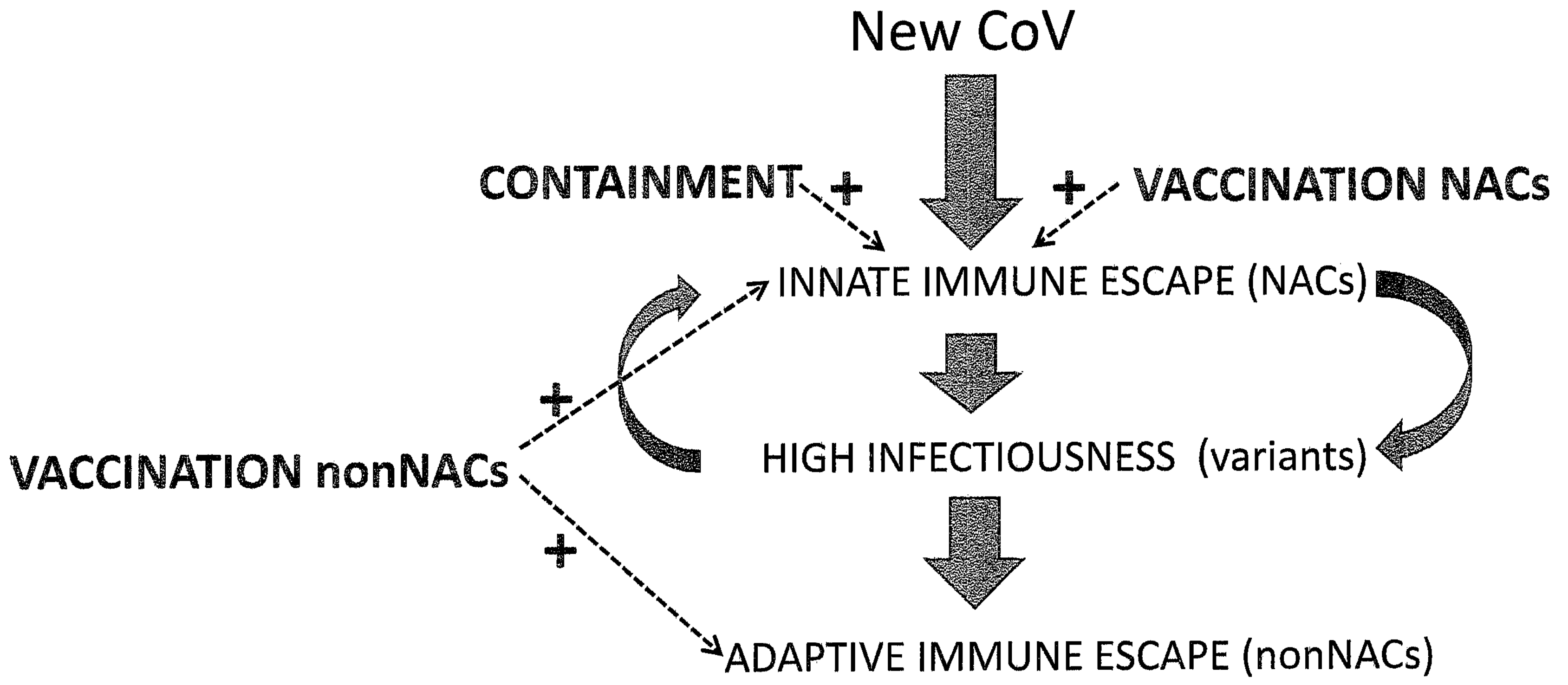
- Untypical course/ waves of pandemic
- Emergence of several much more infectious strains
- Viral shedding (of more infectious variants) in fully vaccinated subjects

↑

Selective (S/ RBD) protein-directed) immune escape

S: Spike protein
RBD: Receptor-binding domain

Mass containment measures and mass vaccination in NACs accelerates INNATE immune escape whereas mass vaccination of nonNACs accelerates INNATE and ADAPTIVE immune escape



New CoV

CONTAINMENT +

+ **VACCINATION NACs**

INNATE IMMUNE ESCAPE (NACs)

HIGH INFECTIOUSNESS (variants)

ADAPTIVE IMMUNE ESCAPE (nonNACs)

VACCINATION nonNACs

+

+

If needed, both NACs and nonNACs can serve as a potential source of immune escape upon human intervention in natural CoV pandemic

ADRIÁN O. DÍAZ DÍAZ

Attorney at Law

February 28, 2021

OPEN LETTER

This communication is not an advertising of our legal services. The purpose of its distribution is to offer an explanation of the FDA Emergency Authorization for the use of vaccines for the COV-SARS-2 and to protect both employees not to be subject to unlawful requirements and employers to avoid legal actions and offer a better work environment. Statements may include the opinion and conclusions of other attorneys and journalist, also legal references are included.

> Since the Food and Drug Administration granted emergency use authorization for two new "vaccines"[1], employers, schools, and other organizations are struggling with whether to require Covid-19 vaccination.
>
> While organizations and employers may be free to encourage their employees, students, and other members to be vaccinated, **federal law provides that**, at least until the vaccine is licensed, individuals must have the option to accept or decline to be vaccinated. Once approved encourage to take the vaccine will be legal if properly justify.
>
> Even though the FDA granted emergency use authorizations for the Pfizer/BioNTech and Moderna vaccines in December 2020, the clinical

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[1] Neither of the Authorized products comply with the traditional definitions for a vaccine.
Vaccine: a substance containing a virus or bacterium in a form that is not harmful, given to a person or animal to prevent them from getting the disease that the virus or bacterium causes; a special substance that you take into your body to prevent a disease, and that contains a weakened or dead form of the disease-causing organism. VACCINE | meaning in the Cambridge English Dictionary.
Vaccine
a. A preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure that upon administration to an individual stimulates antibody production or cellular immunity against the pathogen but is incapable of causing severe infection.
b. A preparation from the cowpox virus that protects against smallpox when administered to an individual. Vaccine | definition of vaccine by Medical dictionary (thefreedictionary.com).

trials the FDA will rely upon to ultimately decide whether to license these vaccines are still underway and are designed to last for approximately two years to collect adequate data to establish if these vaccines are safe and effective enough for the FDA to license.

The abbreviated timelines for the emergency use applications and authorizations means there is much the FDA does not know about these products even as it authorizes them for emergency use, including their effectiveness against asymptomatic infection, death, and transmission of SARS-CoV-2, the virus that causes the disease.

Given the uncertainty about the two vaccines, their EUAs are explicit that each is "*an investigational vaccine not licensed for any indication" and require that all "promotional material relating to the Covid-19 Vaccine clearly and conspicuously … state that* ***this product has not been approved or licensed by the FDA****, but has been authorized for emergency use by FDA*[2]" (emphasis added).

EUAs are clear: Getting these vaccines is voluntary

The same section of the Federal Food, Drug, and Cosmetic Act[3] that authorizes the FDA to grant emergency use authorization also requires the secretary of Health and Human Services to "ensure that individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product."[4]

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[2] (4) Definitions For purposes of this section: (A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262]. (B) The term "emergency use" has the meaning indicated for such term in paragraph (1). (C) The term "product" means a drug, device, or biological product. (D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A). (E) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B). 21 USC § 360bbb-3(a)(4)

[3] 21 U.S. Code § 360bbb–3

[4] Information for Recipients Although informed consent as generally required under FDA regulations is not required for administration or use of an EUA product, section 564 does provide EUA conditions to ensure that recipients are informed about the MCM they receive under an EUA. For an unapproved product (section 564(e)(1)(A)(ii)) and for an unapproved use of an approved product (section 564(e)(2)(A)), the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances: • That FDA has authorized emergency use of the product; • Of the significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown; • That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product; and • Of any available alternatives to the product and of the risks and benefits of available alternatives. See 21 CFR part 50

Likewise, the FDA's guidance on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances … That they have the option to accept or refuse the EUA product …"

Dr. Amanda Cohn, the executive secretary of the CDC's Advisory Committee on Immunization Practices, state that under an EUA, "*vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandatory.*" Cohn later affirmed that this prohibition on requiring the vaccines applies to organizations, including hospitals.

The EUAs for both the Pfizer/BioNTech and Moderna vaccines require facts sheets to be given to vaccination providers and recipients. These fact sheets make clear that getting the vaccine is optional. For example, the one for recipients states that, "*It is your choice to receive or not receive the Covid-19 Vaccine," and if "you decide to not receive it, it will not change your standard of medical care.*"

What this means in practice

When the FDA grants emergency use authorization for a vaccine, many questions about the product cannot be answered. Given the open questions, when Congress granted the authority to issue EUAs, it **chose to require that every individual should be allowed to decide for himself or herself whether or not to receive an EUA product**. The FDA and CDC apparently consider this fundamental requirement of choice important enough that even during the height of the Covid-19 pandemic they reinforced that policy decision when issuing their guidance related to the Covid-19 vaccines.

This means that an organization will likely be at odds with federal law if it requires its employees, students or other members to get a Covid-19 vaccine that is being distributed under emergency use authorization.

State law often prohibits retaliating against an employee for refusing to participate in a violation of federal law. Organizations that require Covid-19 vaccination in violation of federal law may face lawsuits under these state laws not only to block the policy but also for damages and attorneys' fees. Such potentially costly lawsuits can be avoided by refraining from adopting policies that require vaccination or penalize members for choosing not to be vaccinated.

> Organizations may be free to encourage vaccinations through internal communications, through educational events, and through other measures to urge employees to be vaccinated. They can take these measures so long as: (1) they are not viewed as coercive, (2) the organization makes clear the decision regarding whether to receive the vaccine is voluntary, and (3) the measures comply with the requirements in the EUAs and the related regulations for these products.
>
> People across the world have had their lives upended during the last year. The urgency to return to normalcy is felt deeply by many as propaganda may suggest that the used of vaccines may lead to that. As decision-makers at organizations decide on their Covid-19 vaccination policy, they should be careful to not let this passion lead the organization to run afoul of the law.

As to my personal opinion and in my best knowledge, there may be some flaws in the procedures established in Puerto Rico for the administration of the vaccines, since the information of the products, rights of the recipient, disclosures, guidance to report any adverse reactions are not given properly. This omissions may lead to injuries, comply to the right of informed consent, and a lack of reporting to the VAERS (vaccine Adverse Event Reporting System) to better understand the reactions of the products in the population.

Be safe, be responsible, make the right questions and look for the best answers to respect everybody's rights and concerns.

Adrian O. Diaz, Esq.

OMPEI
ORGANIZACIÓN MÉDICA
PERUANA DE
INVESTIGACIÓN

"Año de la universalización de la salud"

ALERTA URGENTE POR LAS VACUNAS COVID-19

Los abajo firmantes, médicos y científicos sin conflictos de intereses, miembros del Consejo Consultivo de la Organización Médica Peruana de Investigación -OMPEI, emitimos este pronunciamiento para alertar a las autoridades de la República del Perú sobre los riesgos que conlleva la implementación masiva y obligatoria en la población de las nuevas vacunas experimentales contra COVID-19.

VISTO

Que, la Organización Mundial de la Salud (OMS) estima que aproximadamente el 10% de la población mundial ya puede haber sido infectada por el SARS-CoV-2, lo cual supondría que hay al menos 780 millones de personas infectadas. Por lo tanto, la letalidad real del COVID-19 (Fallecidos/Contagiados x 100) sería del 0.14% -mucho menor de lo originalmente previsto- llegando a valores similares a la gripe estacional [1].

Que, numerosos estudios científicos sugieren que la inmunidad colectiva contra la infección por SARS-CoV-2 está mucho más extendida de lo que se esperaba. Más del 80% de las personas que no estuvieron expuestas al virus son resistentes a una infección con SARS-CoV-2 debido a que los resfriados comunes causados por los betacoronavirus podrían hacer inmunes a las personas a la infección por SARS-CoV-2 [2]. En términos sencillos esto significa que debido a la circulación global del SARS-Cov-2 y debido a una exposición previa a otros coronavirus [3], es probable que se haya alcanzado el umbral de inmunidad colectiva y que la idea de vacunar a toda la población sea innecesaria y de alto riesgo.

Que, la propuesta de una vacunación masiva implica la negación de la evidencia científica de la existencia de inmunidad natural del cuerpo humano frente al SARS-Cov-2; y el claro intento de suprimir la biología natural evolutiva a través de un nuevo tipo de vacunas científicamente cuestionables.

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[1] https://elpais.com/sociedad/2020-10-05/la-oms-estima-que-el-10-de-la-poblacion-mundial-se-ha-contagiado-de-covid-22-veces-mas-que-los-casos-diagnosticados.html

[2] **SARS-CoV-2-derived peptides define heterologous and COVID-19-induced T cell recognition.** Nelde, A., Bilich, T., Heitmann, J.S. et al. Nat Immunol (2020). https://doi.org/10.1038/s41590-020-00808-x https://www.nature.com/articles/s41590-020-00808-x

[3] **Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals.** A Grifoni, D Weiskopf, S Ramirez et al. Cell 2020 Jun 25;181(7):1489-1501.e15. doi: 10.1016/j.cell.2020.05.015. Epub 2020 May 20. https://pubmed.ncbi.nlm.nih.gov/32473127/

Que, la inoculación de genes nuevos en el cuerpo humano no es vacunación, ya que no se trata de administrar patógenos atenuados o inactivados como antígenos que estimulen la inmunidad, sino de inocular en el cuerpo humano variantes de un prototipo de genes sintéticos inyectables, para que penetren en las células humanas y las haga producir la proteína Spike (S) del virus (es decir, material genético viral en forma de ADN viral en las vacunas vectorizadas o de ARNm viral envuelto en nanopartículas lipídicas con polietilenglicol) lo cual representa un experimento de transgénesis, nunca antes realizado en la historia de la humanidad para conferir inmunidad contra enfermedades infecto-contagiosas de transmisión humana.

Que, las autoridades están cerrando contratos de riesgo con las empresas de biotecnología, a través del compromiso de adquisición prematura de dosis y están implementando medidas para la autorización de inoculaciones masivas en la población, sin que se hayan completado los tiempos mímimos de experimentación requeridos internacionalmente. Esto significa que están habilitando una terapia que se encuentra en la etapa experimental, antes de haber completado las fases preclínicas y clínicas mínimas requeridas para garantizar la seguridad y la eficacia de las mismas.

Que, el desarrollo de vacunas tiene un camino científico largo y que la vacuna más rápida que se ha autorizado en respuesta a un nuevo patógeno humano de preocupación sanitaria, es la vacuna contra el virus del Ébola, cuya investigación llevó casi 6 años. Por este motivo, sería ingenuo pensar que en tiempo récord alguna de las empresas podría ofrecer una vacuna contra COVID-19 que sea científicamente comprobada segura y eficaz [4].

Que, hay vacunas cuya reacción inmunitaria puede dañar, e incluso matar, si se ponen en personas con inmunidad previa. Este es el caso de las vacunas contra la fiebre Q [5], el virus sincicial respiratorio [6] y el dengue [7], de forma que antes de vacunar hay que determinar quién ha tenido contacto natural con el virus, para evitar las graves complicaciones que puede provocar una vacuna cuando ya hay inmunidad natural previa.

Que, antes de realizar la inoculación masiva experimental de la población de cualquiera de las diversas variantes de vacunas contra el SARS-CoV-2, es condición necesaria haber descartado la ocurrencia de una reacción inmunitaria paradójica, tal como la observada en los modelos animales en hurones y felinos en experimentos pre-clínicos, en los cuales la inmunización previa con coronavirus no los protegieron de la infección, sino que, de manera paradójica, quedaron expuestos a padecer una enfermedad peor. Este efecto no debería ser minimizado por las autoridades debido a que dicho fenómeno ya se observó en otros virus -además de coronavirus- como se mencionó, en virus sincitial respiratorio y virus del Dengue.

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[4] **Tortoises, hares, and vaccines: A cautionary note for SARS-CoV-2 vaccine development.** Gregory A.Poland. Vaccine. 2020 Jun 2;38(27):4219-4220. doi: 10.1016/j.vaccine.2020.04.073. PMID: 32387011; PMCID: PMC7252125. https://doi.org/10.1016/j.vaccine.2020.04.073

[5] https://www.health.nsw.gov.au/Infectious/factsheets/Pages/q-fever-vaccine.aspx

[6] **Brief History and Characterization of Enhanced Respiratory Syncytial Virus Disease.** Acosta PL, Caballero MT, Polack FP. Clin Vaccine Immunol. 2015 Dec 16;23(3):189-95. doi: 10.1128/CVI.00609-15. PMID: 26677198; PMCID: PMC4783420. https://pubmed.ncbi.nlm.nih.gov/26677198/

[7] https://www.sciencedirect.com/science/article/abs/pii/S0895435617309721

Que, la posibilidad de ocasionar daños irreversibles en los seres humanos con terapias preventivas en etapa de experimentación, es violatoria de los tratados internacionales de bioética, y conlleva el riesgo potencial de generar enfermedades autoinmunes y neurodegenerativas entre otros efectos adversos graves ya comprobados en voluntarios, así como efectos adversos a mediano y largo plazo -que aún deben ser evaluados- tales como toxicidad, mutagénesis, teratogénesis, carcinogénesis y afectación de la fertilidad en los ciudadanos inoculados.

CONSIDERANDO

Que, actualmente en la República del Perú se llevan adelante ensayos clínicos de fase 2 y 3 con las vacunas experimentales desarrolladas por las empresas **AstraZeneca, Johnson y Johnson, Curevac, Sinopharm, además de una vacuna inhalatoria de Imperial London College,** los médicos, inmunólogos y genetistas estamos alertando acerca de la falta de evaluación del "riesgo-beneficio" sanitario y epidemiológico de autorizar cualquiera de las inoculaciones experimentales, sin que se hayan completado los tiempos y las fases clínicas experimentales requeridas para garantizar la seguridad y la eficacia de lo que se inyecta.

Que, las **vacunas vectorizadas** son transfecciones con material genético viral sintético, que usan vectores de adenovirus con consecuencias negativas demostradas, debido a que pueden resultar en la aparición de virus con tropismo alterado o expandido. El problema principal es la alta inmunogenicidad de los vectores y que su expresión sólo se realiza a corto plazo. Estos vectores no se integran en el genoma del huésped sino que se mantienen en varias copias en forma de plásmido, por lo que la expresión es temporal, lo cual acarrea otro problema: obliga a tener que repetir las inyecciones y se acaba activando el sistema inmune. Los adenovirus han sido modificados para que puedan ser utilizados en terapia génica y no están exentos de efectos epigenéticos [8]. En cuanto a la capacidad del virus vector de modificar el ADN, los adenovirus modificados se usan experimentalmente para la terapia génica justamente con esa idea de modificar el ADN de la persona [9].

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[8] **Nonintegrating Gene Therapy Vectors.** Athanasopoulos T, Munye MM, Yáñez-Muñoz RJ. Hematol Oncol Clin North Am. 2017 Oct;31(5):753-770. doi: 10.1016/j.hoc.2017.06.007. PMID: 28895845.https://pubmed.ncbi.nlm.nih.gov/28895845/

[9] **Adenovirus vectors for gene therapy, vaccination and cancer gene therapy.** Wold, William S M, and Karoly Toth. Current gene therapy Vol. 13,6 (2013): 421-33. doi:10.2174/1566523213666131125095046 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4507798/

La **Universidad de Oxford** (Reino Unido) y **AstraZeneca** han desarrollado una vacuna experimental basada en adenovirus de chimpancé **(ChAdOx1 / AZD1222)** que codifica la glicoproteína spike (S) del SARS-CoV-2. El protocolo del ensayo clínico de fase 1/2 se tuvo que modificar para incluir el uso profiláctico de paracetamol, para reducir las reacciones locales y sistémicas a la vacuna (dolor e hipersensibilidad en el lugar de la inyección, escalofríos, fatiga, fiebre, dolor de cabeza, malestar, dolores musculares y náuseas) [10]. El ensayo de fase 1/2 se pausó después de que un participante desarrolló síntomas neurológicos, que luego se relacionaron con la Esclerosis Múltiple. Un ensayo de fase 3 de la vacuna AZD1222 en adultos comenzó en agosto de 2020 en varios lugares del mundo (también en la Argentina y el Perú) pero se pausó después de que dos receptores de la vacuna desarrollaron síntomas compatibles con Mielitis Transversa [11] [12]. Recientemente, las autoridades sanitarias reportaron el lamentable fallecimiento de un médico de 28 años, voluntario de la vacuna de AstraZéneca en Brasil [13].

Las compañías farmacéuticas Janssen, de **Johnson & Johnson** han iniciado un ensayo de fase 3 aleatorizado, doble ciego, controlado con placebo de su **vacuna vectorizada con adenovirus humano Ad26.COV2.S** con replicación defectuosa, que expresa la glicoproteína spike (S). Los resultados preclínicos indican que una sola inmunización por vía intramuscular con esta vacuna de adenovirus serotipo 26 sin adyuvante, induciría respuestas de anticuerpos neutralizantes y proporcionaría protección contra el SARS-CoV-2 en macacos rhesus [14]. La compañía no ha publicado detalles sobre el perfil de seguridad y la eficacia de la vacuna, sin embargo el pasado 23 de septiembre de 2020 comenzó un ensayo de fase 3 en Perú; Argentina; Brasil; Chile; Colombia; México; Filipinas; Sudáfrica; Ucrania y Estados Unidos (Ensayo clínico registrado NCT04505722) [15].

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[10] **Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial.** Folegatti PM, Ewer KJ, Aley PK,et al. Oxford COVID Vaccine Trial Group. Lancet. 2020 Aug 15;396(10249):467-478. doi: 10.1016/S0140-6736(20)31604-4. https://pubmed.ncbi.nlm.nih.gov/32702298/

[11] https://www.clinicaalemana.cl/articulos/detalle/2020/mielitis-transversa-como-efecto-de-la-vacuna-para-el-covid-19

[12] https://www.rfi.fr/es/salud/20200924-mielitis-transversa-porqu%C3%A9-astrazeneca-suspendi%C3%B3-un-tiempo-sus-ensayos-de-la-vacuna-de-la-covid-19

[13] https://www.lanacion.com.ar/el-mundo/coronavirus-muere-voluntario-prueba-vacuna-astrazeneca-nid2485571

[14] **Prime-boost vaccination of mice and Rhesus macaques with two novel adenovirus vectored COVID-19 vaccine candidates.** Shengxue Luo, Panli Zhang, Bochao Liu, Chan Yang, Chaolan Liang, Qi Wang, Ling Zhang, Xi Tang, Jinfeng Li, Shuiping Hou, Jinfeng Zeng, Yongshui Fu, Jean-Pierre Allain, Tingting Li, Yuming Zhang, Chengyao Li
bioRxiv 2020.09.28.311480; doi: https://doi.org/10.1101/2020.09.28.311480

[15] **Ad26-vector based COVID-19 vaccine encoding a prefusion stabilized SARS-CoV-2 Spike immunogen induces potent humoral and cellular immune responses.** R. Bos, L. Rutten, J. van der Lubbe, et al. bioRxiv 2020.07.30.227470; doi: https://doi.org/10.1101/2020.07.30.227470 https://www.biorxiv.org/content/10.1101/2020.07.30.227470v1.full.pdf

El uso de los vectores de adenovirus recombinantes para las vacunas COVID-19 genera preocupación debido a que hace más de una década, estudios internacionales demostraron que las vacunas con vector de adenovirus serotipo Ad5 predisponen a un mayor riesgo de adquisición del VIH-1 entre los hombres vacunados [16] [17]. Sobre la base de estos hallazgos, el uso de un vector de adenovirus no replicante para la inmunización contra el SARS-CoV-2 podría aumentar de manera similar el riesgo de adquirir el SIDA entre los hombres que reciben la vacuna [18]. Los ensayos de otras vacunas (no relacionadas con el VIH) que utilizaron vectores similares en áreas de alta prevalencia del VIH-1 también demostraron un mayor riesgo de contraer el VIH-1 en la población vacunada. La explicación parece estar en la inmunidad que se genera contra el vector: las células T CD4 específicas contra el adenovirus podrían tener una mayor susceptibilidad a la infección por virus del SIDA [19]. Preocupa entonces, el hecho de que sea *peor el remedio que la enfermedad:* hay que considerar que, por evitar una infección respiratoria que tiene una sobrevida del 99% con los tratamientos actuales, la utilización de vacunas con vectores de adenovirus pueda inducir una predisposición a infección por el VIH-1 u otros virus.

Un efecto indeseado adicional es la inyección repetida de material genético humano canceroso derivado del tipo celular HELA en la que se cultivan los vectores, en biorreactores a gran escala en los que se produce la vacuna. El linaje celular al cual pertenecen estas células deriva de una muestra de cáncer cérvico-uterino obtenida el 8 de febrero de 1951; son células cancerosas inmortales, que pueden cultivarse en el laboratorio constantemente. El material genético canceroso se arrastra en la vacuna y se inyecta en las personas, con consecuencias impredecibles para la salud.

Que, las **vacunas de ARN** (de las empresas **Moderna, Pfizer/BioNtech, CureVac**) son inyecciones de ARNs mensajeros foráneos recubiertos con nanopartículas lipídicas con polietilenglicol, con el fin de evadir los mecanismos del cuerpo y permitirle ingresar en las células sin ser degradado por las barreras naturales del organismo. Las empresas de biotecnología se esfuerzan en repetir el hecho de que las vacunas ARNm no tienen la capacidad de ingresar al núcleo para modificar el ADN. Explican que el ARNm de la vacuna sólo va a codificar la glicoproteína spike (S) y se va limitar a transcribirla en el citoplasma celular. Llama la atención que se abstengan de mencionar el mecanismo de regulación epigenética que tiene el ARNm. La capacidad de regular directamente la expresión de los genes es un mecanismo ampliamente reconocido por la biología molecular: el silenciamiento génico mediado por ácidos ribonucleicos, los llamados siRNA [20].

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[16] **Continued follow-up of Phambili phase 2b randomized HIV-1 vaccine trial participants supports increased HIV-1 acquisition among vaccinated men.** Moodie Z, Metch B, Bekker LG et al. PLoS One. 2015; 10e0137666. https://pubmed.ncbi.nlm.nih.gov/26368824/

[17] **Efficacy assessment of a cell-mediated immunity HIV-1 vaccine (the Step Study): a double-blind, randomised, placebo-controlled, test-of-concept trial.** Buchbinder SP, Mehrotra DV, Duerr A et al. Lancet. 2008; 372: 1881-1893. https://pubmed.ncbi.nlm.nih.gov/19012954/

[18] **Use of adenovirus type-5 vectored vaccines: a cautionary tale.** S.P. Buchbinder, M. J.McElrath, C.Dieffenbach and L. Corey. The Lancet. Volume 396, ISSUE 10260, October 31, 2020 DOI:https://doi.org/10.1016/S0140-6736(20)32156-5. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32156-5/fulltext

[19] **Human adenovirus-specific T cells modulate HIV-specific T cell responses to an Ad5-vectored HIV-1 vaccine.** Frahm N, DeCamp AC, Friedrich DP et al. J Clin Invest. 2012; 122: 359-367 https://pubmed.ncbi.nlm.nih.gov/22201684/

Por lo tanto, las vacunas ARNm tienen la capacidad potencial de modificar el ADN humano, induciendo o silenciando distintos genes de nuestro genoma.
Por ello (y para facilitar el entendimiento a las personas no especialistas) decimos que son **vacunas transgénicas**, porque trasgreden el ADN nativo del ser humano y conllevan el riesgo de generar modificaciones genéticas de carácter transitorias o permanentes y en grado desconocido, sin control real de sus consecuencias y escalas, sin poder garantizar que no se van a inducir alteraciones irreversibles de la condición humana.

CureVac desarrolló una vacuna de mRNA no modificado encapsulado en nanopartículas lipídicas que codifica la glicoproteína spike (S) estabilizada y de longitud completa **(CVnCoV)**. En los ensayos preclínicos, la inmunización con CVnCoV indujo respuestas humorales con anticuerpos neutralizantes de virus en ratones y hámsteres y respuestas células T CD4+ y CD8+ en ratones [21]. Reportaron que la vacunación con CVnCoV protegió los pulmones de hámster de la reinfección con el SARS-CoV-2 de tipo salvaje. No detectaron signos de enfermedad potenciada por la vacuna cuando se analizaron los hámsteres vacunados con una dosis subóptima de CVnCoV.

Con estos escasos antecedentes preclínicos, publicados online el día 23 de octubre de 2020 sin revisión por pares, CureVac lleva adelante ensayos clínicos de fase 1 y 2 en Alemania, Bélgica, en el Instituto de Investigación Nutricional de Lima, Perú y en el Centro de vacunación internacional CEVAXIN Panama Clinic, de Panamá (Ensayos clínicos registrados NCT04449276 y NCT04515147).

Esto quiere decir que se están usando modelos de desafío humano como método para avanzar rápidamente en el desarrollo de las vacunas y se está comprometiendo a los gobiernos a adquirir millones de dosis, presuponiendo seguridad, eficacia y beneficio. Esto es una ingenuidad y no debe suponerse, debido a que la carga de la prueba recae en el desarrollador de la vacuna y es quien debe demostrar con datos experimentales prolongados en el tiempo que esas presuposiciones están científicamente justificadas con todo el peso de prueba científico. Este tipo de vacunas son justamente las más preocupantes, ya que vacunas de ARNm no han sido probadas nunca en la historia de la inmunización con el fin evitar la transmisión de enfermedades infecto-contagiosas de transmisión entre seres humanos y deberían exigirse los tiempos de investigación adecuados.

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[20] https://www.sap.org.ar/docs/publicaciones/archivosarg/2012/v110n2a08.pdf

[21] **mRNA based SARS-CoV-2 vaccine candidate CVnCoV induces high levels of virus neutralizing antibodies and mediates protection in rodents.** Susanne Rauch, Nicole Roth, Kim Schwendt, et al. doi: https://doi.org/10.1101/2020.10.23.351775 https://www.biorxiv.org/content/10.1101/2020.10.23.351775v1.full.pdf

Una consideración extra y no menos importante reside en que los virus de ARN mutan con gran rapidez y ya se han identificado múltiples mutaciones del SARS-CoV-2 [22]; por lo tanto, el desarrollo de este tipo de vacunas de ARNm podría verse obstaculizado si el virus muta y evade la inmunidad a la glucoproteína Spike (S) utilizada para construir la vacuna.

Que, las **vacunas de partículas virales artificiales inactivadas** también son producidas en cultivos celulares a gran escala en biorreactores, con purificación y estándares de calidad que no tenemos certeza ni capacidad de evaluar. Este tipo de estrategia resulta muy apresurada, sin haber descartado hasta la fecha que no provocan una reacción inmunitaria paradójica, (también conocido como "mejora dependiente de anticuerpos") [23] como la que se vio en los modelos animales en hurones, felinos y en primates no humanos en los experimentos pre-clínicos [24], en los cuales la inmunización previa con virus corona no los protegieron de la infección, sino que, de manera paradójica, quedaron expuestos a padecer una enfermedad peor. Este efecto no debería ser minimizado debido a que ya se observó -además de coronavirus de tipo SARS-con otros virus tales como el virus sincitial respiratorio (VSH)[25] el sarampión[26] y el virus del Dengue [27].

Son claras las preocupaciones con respecto al potencial de padecer una "mejora dependiente de anticuerpos" en individuos que sean reinfectados con SARS-CoV-2 después de la vacunación, con cualquiera de las vacunas candidatas para COVID-19, debido a que desde el brote de SARS-CoV-1 en 2002, la "mejora dependiente de anticuerpos" representa un obstáculo para el desarrollo de la vacuna contra los virus corona y debe ser cuidasosamente evaluado.

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[22] **Molecular architecture of early dissemination and massive second wave of the SARS-CoV-2 virus in a major metropolitan area.** Long SW, Olsen RJ, Christensen PA. medRxiv. 2020 doi: 10.1101/2020.09.22.20199125. published online Sept 23 https://www.medrxiv.org/content/10.1101/2020.09.22.20199125v3.full.pdf

[23] **Is antibody-dependent enhancement playing a role in COVID-19 pathogenesis?** Negro F. Swiss Med Wkly. 2020 Apr 16;150:w20249. doi: 10.4414/smw.2020.20249.https://pubmed.ncbi.nlm.nih.gov/32298458/

[24] **Immunodominant SARS Coronavirus Epitopes in Humans Elicited both Enhancing and Neutralizing Effects on Infection in Non-human Primates.** Wang, Q., Zhang, L., Kuwahara, K., Li, L., Liu, Z., Li, T., Zhu, H., Liu, J., Xu, Y., Xie, J., et al. (2016). ACS infectious diseases. 2(5), 361–376. DOI: 10.1021/acsinfecdis.6b00006. https://pubs.acs.org/doi/pdf/10.1021/acsinfecdis.6b00006

[25] **Immunological Lessons from Respiratory Syncytial Virus Vaccine Development.** Ruckwardt, T.J., Morabito, K.M., and Graham, B.S.(2019). Immunity. 51(3), 429–442. DOI: 10.1016/j.immuni.2019.08.007. https://www.sciencedirect.com/science/article/pii/S1074761319303334

[26] **Immunoglobulin g antibody-mediated enhancement of measles virus infection can bypass the protective antiviral immune response.** Iankov ID, Pandey M, Harvey M, Griesmann GE, Federspiel MJ, Russell SJ. J Virol. 2006;80:8530–8540. https://pubmed.ncbi.nlm.nih.gov/16912303/

[27] **Dengvaxia sensitizes seronegatives to vaccine enhanced disease regardless of age.** Halstead, S.B. (2017) Vaccine. 35. pp. 6355-6358 https://www.sciencedirect.com/science/article/pii/S0264410X17313610

ADVERTENCIA

Las autoridades quedan entonces debidamente advertidas del riesgo potencial de que los individuos vacunados con la proteína spike (S) de SARS-CoV-2 (objetivo principal de todas las vacunas candidatas actuales contra COVID-19) podrían generar anticuerpos no neutralizantes, lo que podría causar complicaciones inducidas por la vacunación o un aumento de la enfermedad COVID-19, razón por la cual los individuos vacunados podrían quedar sensibilizados y podrían experimentar un aumento de la enfermedad del COVID-19 en un futuro previsible [28] [29].

Por todos estos argumentos y antecedentes científicos, es necesario **respetar los tiempos** de los ensayos clínicos para asegurarse que a mediano y largo plazo no van a ocasionar daños irreversibles en los seres humanos, por el riesgo en un grado desconocido de generar modificaciones genéticas de carácter transitorias o permanentes y asegurarse que las inyecciones no van a provocar **enfermedades autoinmunes, neurodegenerativas** u otros efectos adversos graves ya descritos en voluntarios. Es preciso descartar que a mediano y largo plazo no provocarán toxicidad, mutagénesis, teratogénesis, carcinogénesis y que no habrá afectación de la fertilidad en los ciudadanos inoculados.

Sinopharm está probando dos vacunas de virus completo inactivado con adyuvante (sales de aluminio) desarrollada por el Instituto de Productos Biológicos de Wuhan. Se han publicado los datos de los estudios de fase 1 y 2 [30]. También se ha iniciado un ensayo clínico de fase 1/2 en personas de 6 años o más y ensayo clínico de fase 3 que tiene previsto inscribir voluntarios en Perú, Argentina, Marruecos, Jordania, Emiratos Árabes Unidos y Baréin. Las vacunas que se destinen a la población deben ser seguras y efectivas. Sería ingenuo pensar que en tiempo récord alguna de las empresas podría ofrecer una vacuna contra COVID-19 que sea científicamente comprobada segura y eficaz [31].

Que, es urgente e ineludible poder descartar posibles efectos adversos en la fertilidad humana y para ello es necesario exigir a las empresas farmacéuticas que los ensayos clínicos con las vacunas experimentales se realicen durante un tiempo prolongado suficiente (mínimo de dos años como lo exige la legislación internacional).

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[28] **Is COVID-19 receiving ADE from other coronaviruses?** Jason A.Tetro. Microbes and Infection Volume 22, Issue 2, March 2020, Pages 72-73. https://doi.org/10.1016/j.micinf.2020.02.006

[29] **Immunity after COVID-19: protection or sensitization?** Antoine Danchin, doi: https://doi.org/10.1101/2020.05.21.20108860. https://www.medrxiv.org/content/10.1101/2020.05.21.20108860v2

[30] **Effect of an inactivated vaccine against SARS-CoV-2 on safety and immunogenicity outcomes: interim analysis of 2 randomized clinical trials.** Xia S, Duan K, Zhang Y. JAMA. 2020;324:951–960. https://pubmed.ncbi.nlm.nih.gov/32789505/

[31] **Caution urged on SARS vaccines.** Marshall E, Enserink M. Medicine. Science. 2004 Feb 13;303(5660):944-6. doi: 10.1126/science.303.5660.944. PMID: 14963300 DOI: 10.1126/science.303.5660.944. https://pubmed.ncbi.nlm.nih.gov/14963300/

Desde la aparición del brote del Síndrome Respiratorio Agudo Severo (SARS-CoV-1) del 2002 en Guandong, China y del brote de MERS en 2012 en Arabia Saudita, se sabe que los coronavirus de tipo SARS dañan múltiples órganos y se ha demostrado el daño irrevesible que provoca en el sistema reproductivo masculino [32]. El impacto de la infección por el nuevo SARS-CoV-2 sobre la fertilidad masculina también ha sido recientemente demostrado [33].

El daño testicular provocado por el SARS-CoV-2 se explicaría por la alta expresión del receptor ACE2 (homólogo de la enzima convertidora de angiotensina 2) en la gónada masculina. El receptor de alta afinidad de la proteína viral Spike (S) sería la enzima ACE2 que tiene expresión mayoritaria en testículo, y también en ovarios y embrión, y desempeña una función promordial en la reproducción humana [34] [35] [36] [37] (Figuras 1 y 2).

Figura 1: Expresión de la enzima ACE2 en los tejidos humanos [38].

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[32] **Orchitis: A Complication of Severe Acute Respiratory Syndrome (SARS).** Jian Xu, Lihua Qi, Xiaochun Chi, et al. Biology of Reproduction, Volume 74, Issue 2, 1 February 2006, Pages 410–416, https://doi.org/10.1095/biolreprod.105.044776

[33] **Could SARS-CoV-2 affect male fertility?** Vishvkarma R, Rajender S. Andrologia. 2020 Oct;52(9):e13712. doi: 10.1111/and.13712. Epub 2020 Jun 23. PMID: 32578263; PMCID: PMC7361071. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7361071/

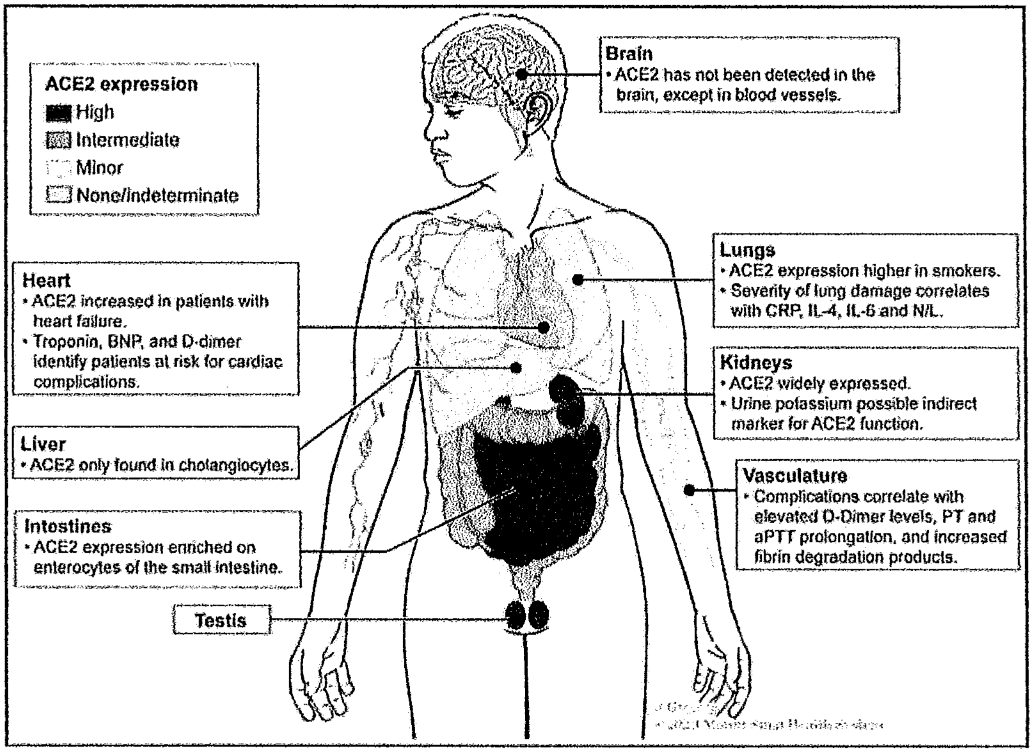
[34] **Angiotensin-converting enzymes play a dominant role in fertility.** Pan PP, Zhan QT, Le F, Zheng YM, Jin F. Int J Mol Sci. 2013 Oct 21;14(10):21071-86. doi: 10.3390/ijms141021071. PMID: 24152441; PMCID: PMC3821659. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3821659/

[35] **A human homolog of angiotensin-converting enzyme. Cloning and functional expression as a captopril-insensitive carboxypeptidase.** Tipnis SR, Hooper NM, Hyde R, Karran E, Christie G, Turner AJ. J Biol Chem. 2000 Oct 27;275(43):33238-43. doi: 10.1074/jbc.M002615200. PMID: 10924499.https://www.jbc.org/content/275/43/33238.full.pdf

[36] **A Novel Angiotensin-Converting Enzyme–RelatedCarboxypeptidase (ACE2) Converts Angiotensin I to Angiotensin 1-9.** Mary Donoghue, Frank Hsieh, Elizabeth Baronas et al. Circulation Research. 2000;87:e1–e9. Originally published 1 Sep 2000https://doi.org/10.1161/01.RES.87.5.e1

[37] **Immunology of COVID-19: Current State of the Science.** N. Vabret, G.J.Britton,C Gruber et al. Immunity 52, June 16, 2020 ª 2020 https://doi.org/10.1016/j.immuni.2020.05.002

[38] Figura extraída de: **Immunology of COVID-19: Current State of the Science.** N. Vabret, G.J.Britton,C Gruber et al. Immunity 52, June 16, 2020 ª 2020 https://doi.org/10.1016/j.immuni.2020.05.002


ACE2 expression
▇ High
▨ Intermediate
Minor
☐ None/indeterminate
Brain
• ACE2 has not been detected in the brain, except in blood vessels.
Lungs
• ACE2 expression higher in smokers.
• Severity of lung damage correlates with CRP, IL-4, IL-6 and N/L.
Heart
• ACE2 increased in patients with heart failure.
• Troponin, BNP, and D-dimer identify patients at risk for cardiac complications.
Kidneys
• ACE2 widely expressed.
• Urine potassium possible indirect marker for ACE2 function.
Liver
• ACE2 only found in cholangiocytes.
Vasculature
• Complications correlate with elevated D-Dimer levels, PT and aPTT prolongation, and increased fibrin degradation products.
Intestines
• ACE2 expression enriched on enterocytes of the small intestine.
Testis

Se demostró recientemente que la expresión de ACE2 se detecta principalmente en enterocitos, túbulos renales, vesícula biliar, cardiomiocitos, células reproductoras masculinas, trofoblastos placentarios, células ductales, ojos y vasculatura. En el sistema respiratorio, la expresión fue muy limitada, con poca o ninguna expresión en un subconjunto de células y tan sólo en unos pocos individuos, confirmando que la enzima ACE 2 no se encuentra expresada en pulmón [39].

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[39] **The protein expression profile of ACE2 in human tissues.** Hikmet F, Méar L, Edvinsson Å, Micke P, Uhlén M, Lindskog C. Mol Syst Biol. 2020 Jul;16(7):e9610. doi: 10.15252/msb.20209610. PMID: 32715618; PMCID: PMC7383091 https://pubmed.ncbi.nlm.nih.gov/32715618/

Expresión del ARNm de ACE2 en los tejidos humanos

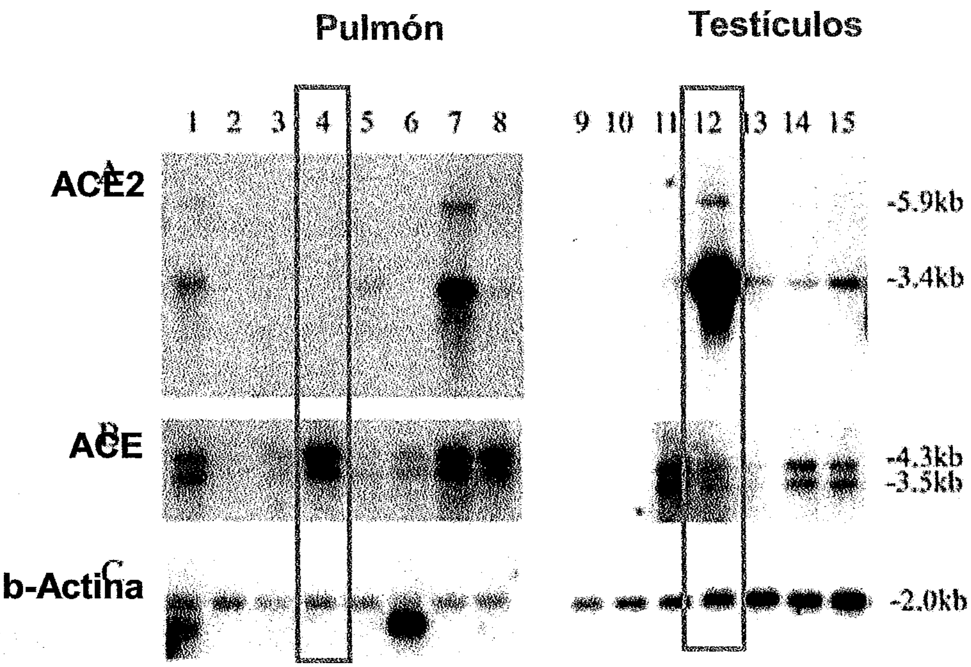

FIG. 2. **Northern blot analysis of ACEH mRNA expression in various human tissues.** Multiple tissue Northern blots (CLONTECH) containing 2 μg of poly(A)$^+$ RNA per lane were probed with ^{32}P-labeled cDNA fragments of either ACEH (*A*), ACE (*B*), or β-actin (*C*). Lanes are as follows: *1*, heart; *2*, brain; *3*, placenta; *4*, lung; *5*, liver; *6*, skeletal muscle; *7*, kidney; *8*, pancreas; *9*, spleen; *10*, thymus; *11*, prostate; *12*, testis; *13*, ovary; *14*, small intestine; and *15*, colon.

J Biol Chem. 2000 Oct 27;275(43):33238-43. doi: 10.1074/jbc.M002615200

Figura 2: Expresión del RNAm de la enzima ACE2 en los tejidos humanos [40]

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[40] **A human homolog of angiotensin-converting enzyme. Cloning and functional expression as a captopril-insensitive carboxypeptidase.** Tipnis SR, Hooper NM, Hyde R, Karran E, Christie G, Turner AJ. J Biol Chem. 2000 Oct 27;275(43):33238-43. doi: 10.1074/jbc.M002615200. PMID: 10924499. https://pubmed.ncbi.nlm.nih.gov/10924499/

La orquitis autoinmune es una complicación demostrada del SARS-CoV. En los pacientes que han pasado por una infección COVID-19 natural, de curso leve o moderado, no se observan secuelas ni daño en los testículos ni la calidad del semen, pero si se deben seguir y evaluar las funciones reproductivas en pacientes varones con COVID-19 severo recuperados [41].

Los cambios patológicos que se observaron en los testículos de pacientes que murieron de SARS y MERS sugirieron que el virus causaba epididimitis y orquitis autoinume (intensa inflamación testicular causada por la respuesta inmune celular y los anticuerpos).

Se ha podido observar extensa destrucción de las células germinales, con pocos o sin espermatozoides, con la membrana basal engrosada, fibrosis peritubular, infiltración de linfocitos y macrófagos, congestiones vasculares, y anticuerpos autoinmunes: depósitos de IgG muy extensa en el epitelio seminífero, el intersticio, células germinales degeneradas y las células de Sertoli, todo lo cual indica que es la respuesta inmune específica contra el virus la causa principal del daño testicular, ya que no se encontraron virus SARS en los testículos. No se detectaron secuencias del genoma del SARS en los testículos afectados, se pudo comprobar que los coronavirus no ingresan a los túbulos seminíferos ni se detectan en muestras de semen [42] [43], lo que sugiere que el impacto en los testículos se debe a la respuesta inmune contra la proteína Spike (S) del SARS-CoV, por el depósito de las inmunoglobulinas.

Por estos hallazgos, antes de aprobar una inoculación masiva en la población con cualquiera de las vacunas contra COVID-19, resulta necesario evaluar en los ensayos clínicos a mediano y largo plazo que la respuesta inmune inducida por las vacunas no van a causar epididimitis, orquitis y/o puedan provocar infertilidad por depósito de los anticuerpos en el tejido testicular.

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[41] **Is there an impact of the COVID-19 pandemic on male fertility?** The ACE2 connection. Younis JS, Abassi Z, Skorecki K. Am J Physiol Endocrinol Metab. 2020 Jun 1;318(6):E878-E880. doi: 10.1152/ajpendo.00183.2020. Epub 2020 May 18. PMID: 32421367; PMCID: PMC7276979. https://pubmed.ncbi.nlm.nih.gov/32421367/

[42] **scRNA-seq Profiling of Human Testes Reveals the Presence of the ACE2 Receptor, A Target for SARS-CoV-2 Infection in Spermatogonia, Leydig and Sertoli Cells.** Wang Z, Xu X. Cells. 2020 Apr 9;9(4):920. doi: 10.3390/cells9040920. PMID: 32283711; PMCID: PMC7226809. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7226809/

[43] **Assessment of SARS-CoV-2 in human semen-a cohort study.** Holtmann N, Edimiris P, Andree M, Doehmen C, Baston-Buest D, Adams O, Kruessel JS, Bielfeld AP. Fertil Steril. 2020 Aug;114(2):233-238. doi: 10.1016/j.fertnstert.2020.05.028. Epub 2020 May 29. PMID: 32650948; PMCID: PMC7256599. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7256599/

A estos antecedentes médicos y científicos nos referimos, principlamente, cuando alertamos que la inmunización con vacunas contra COVID-19 pueden afectar la fertilidad. El derecho a la descendencia no puede verse afectado por ninguna terapia preventiva experimental y ese derecho lo tienen que garantizar las empresas, pero dados los tiempos reducidos de desarrollo de estas vacunas, no están permitiendo de manera adecuada la evaluación y el registro de los efectos adversos a mediano y largo plazo.

Por los motivos expuestos,

SOLICITAMOS

1- Que, se evalúe de manera independiente la verdadera situación epidemiológica-sanitaria, la eficacia de los tratamientos disponibles y el estado real de la inmunidad natural contra el SARS-CoV-2 de la población.

2- Que, no se exponga a los ciudadanos a una práctica masiva experimental injustificada, que podría desencadenar un desastre sanitario de gran magnitud.

3- Que, se respete la transparencia pública de la información, rechazando el resguardo de cláusulas confidenciales requerido por las empresas transnacionales y que se prioricen los estudios y ensayos clínicos nacionales de posibles terapias, medicamentos y vacunas para tratar la enfermedad Covid-19.

4- Que, no se conceda la inmunidad legal y patrimonial a los laboratorios productores de las vacunas, a fin de no flexibilizar el esmero que deben aplicar para reforzar las condiciones de eficacia e inocuidad de la vacuna en desarrollo.

5- Que, no se permita bajo ninguna excusa la prórroga de Jurisdicción de la Justicia, en detrimento de los derechos y garantías constitucionales de los habitantes de la República del Perú.

Lima, 15 de noviembre de 2020

Dra, Roxana Bruno Dra. Chinda Brandolino Dra. María José Martinez Albarracín Dra. Natalia Prego Dr. Luis Marcelo Martinez, Dr. Mario Borini Dr. Mauricio Castillo Dr. Silvana Baztán Dr, Eduardo Yabes Dra Marcela Witt Dr. Lorenzo Colque

Abog. Rosa María Apaza, Presidenta de la OMPEI

PETITIONER:
Dr. med. Wolfgang Wodarg
[redacted]
Germany

December 1, 2020

CO-PETITIONER:
Dr. Michael Yeadon
[redacted] England, CT3 1RT

TO:
European Medicines Agency
Committee for human medicinal products (CHMP)
COVID-19 EMA pandemic Task Force (COVID-ETF)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

info@ema.europa.eu
press@ema.europa.eu

!! URGENT !!

PETITION/MOTION FOR ADMINISTRATIVE/REGULATORY ACTION REGARDING CONFIRMATION OF EFFICACY END POINTS AND USE OF DATA IN CONNECTION WITH THE FOLLOWING CLINICAL TRIAL(S):

PHASE III - EUDRACT NUMBER: 2020-002641-42

SPONSOR PROTOCOL NUMBER: C4591001

SPONSOR: BIONTECH SE (SOCIETAS EUROPAEA), AN DER GOLDGRUBE 12, 55131 MAINZ, GERMANY

AND ANY OTHER ONGOING CLINICAL TRIALS OF VACCINE CANDIDATES DESIGNED TO STOP TRANSMISSION OF THE VIRUS FROM THE VACCINE RECIPIENT TO OTHERS AND/OR TO PREVENT COVID-19 OR MITIGATE SYMPTOMS OF COVID-19 FOR WHICH PCR RESULTS ARE THE PRIMARY EVIDENCE OF INFECTION WITH SARS-COV-2

ADMINISTRATIVE/REGULATORY STAY OF ACTION

This petition for a stay of action is submitted by the undersigned ("**Petitioner**" or "**Lead Petitioner**") to request the EMA a) stay the Phase III clinical trial(s) of BNT162b (EudraCT Number 2020-002641-42) in the EU (current protocol country: Germany) until study design is amended to conform with the requests in the "Action Requested" section (**B.**) below; and b) stay all other clinical trials of vaccine candidates designed to stop transmission of the virus from the

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vaccine recipient to others and/or prevent or mitigate symptoms of COVID-19 for which PCR results are the primary evidence of infection.

Because of the compelling need to ensure the safety and efficacy of any COVID-19 vaccine licensed by the EMA (and/or the German Paul-Ehrlich-Institut), and to allow Petitioner the opportunity to seek appropriate emergency judicial relief should the EMA deny its Petition, **Petitioner respectfully requests that EMA act on the instant Petition immediately.**

A. DECISIONS INVOLVED

I. Approval of trial design and/or decision to not challenge trial design for Phase III trial of BNT162 (EudraCT Number 2020-002641-42)

II. Approval of trial design and/or decision to not challenge trial design of all other clinical trials of vaccine candidates designed to stop transmission of the virus from the vaccine recipient to others and/or to prevent or mitigate symptoms of COVID-19 for which PCR results are the primary evidence of infection.

B. ACTION REQUESTED

I. Stay the Phase III trial of BNT162 in the protocol country Germany and in any other EU protocol countries (as applicable) until study design is amended to provide that:

Before an Emergency Authorization/Conditional Approval and/or Unrestricted Authorization is issued for the Pfizer/BioNTech vaccine, all "endpoints" or COVID-19 cases used to determine vaccine efficacy in the Phase 3 or 2/3 trials should have their infection status confirmed by appropriate Sanger sequencing (as described in section C. III. below), given a) the high cycle thresholds used in some trials; and b) design flaws of certain RT-qPCR tests identical to or modeled after what is sometimes called the "Drosten-Test".

II. Stay the clinical trials of all vaccine candidates designed to stop transmission of the virus from the vaccine recipient to others and/or to prevent or mitigate symptoms of COVID-19 for which PCR results are the primary evidence of infection until study design is amended to provide that:

Before an Emergency Authorization/Conditional Approval and/or Unrestricted Authorization is issued for vaccine designed to stop transmission of the virus from the vaccine recipient to others and/or to prevent or mitigate symptoms of COVID-19, all "endpoints" or COVID-19 cases used to determine vaccine efficacy should have their infection status confirmed by appropriate Sanger sequencing (as described in section B. III. below), given a) the high cycle thresholds used in some trials; and b) design flaws of certain RT-qPCR tests identical to or modeled after what is sometimes called the "Drosten-Test".

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III. High cycle thresholds, or Ct values, in RT-qPCR test results have been widely acknowledged to lead to false positives. Also, a group of scientists and researchers have recently called for a retraction of the paper that describes the so called "Drosten-Test" (sometimes also being referred to as the "Corman-Drosten protocol" - a specific RT-qPCR assay described by Corman,Victor M., Drosten, Christian and others in "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR." Euro Surveillance 2020;25(3):pii=2000045. https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045).

All RT-qPCR-positive test results used to categorize patient as "COVID-19 cases" in the trials and used to qualify the trial's endpoints should be verified by Sanger sequencing to confirm that the tested samples in fact contain a unique SARS-CoV-2 genomic RNA. Congruent with FDA and EMA requirements for a confirmed diagnosis of human papillomavirus (HPV) using PCR, the sequencing electropherogram must show a minimum of 100 contiguous bases matching the reference sequence with an Expected Value (E Value) <10-30 for the specific SARS-CoV-2 gene sequence based on a BLAST search of the GenBank database (aka NCBI Nucleotide database).

C. STATEMENT OF GROUNDS

I. As detailed herein, (i) without the requested stay, the Petitioner and many EU residents/citizens will suffer irreparable harm, (ii) the request is not frivolous and is being pursued in good faith, (iii) the request demonstrates sound public policy, and (iv) the public interest favors granting a stay.

II. Petitioner deems the current study designs for the Phase II/III trials of BNT162b ("the Pfizer/BioNTech trial") to be inadequate to accurately assess efficacy. Petitioner also deems the designs of clinical trials of vaccine candidates designed to stop transmission of the virus from the vaccine recipient to others and/or to prevent or mitigate symptoms of COVID-19 for which PCR results are the primary evidence of infection to be inadequate to accurately assess efficacy.

III. Petitioner and the public will suffer irreparable harm if the actions requested herein are not granted, because once the EMA (and other appropriate bodies in the various EU member states) approves the COVID-19 vaccines in question, both governments of EU member states and employers in the EU are most likely going to recommend them for widespread use. If the assignment of cases and non-cases during the course of the trials is not accurate, the vaccines will not have been properly tested. If the vaccines are not properly tested, important public policy decisions regarding its use will be based on misleading evidence. The medical and economic consequences to EU member states and their residents/citizens could hardly be higher.

IV. Furthermore, if the vaccines are approved without an appropriate and accurate review of efficacy, then any potential acceptance or mandate of these vaccines is likely to be based on inaccurate evidence regarding the vaccine, namely that it will stop transmission of the virus from the vaccine recipient to others and/or that it will reduce COVID-19 disease and deaths. The Pfizer/BioNTech trial protocol and other trial protocols are currently not designed to determine whether either of those objectives can be met; and even if it was, if cases cannot be reliably identified, neither objective could be reliably met.

V. The public interest also weighs strongly in favor of the requested relief because improving the accurate determination of primary endpoints (i) will comport with the best scientific practices, (ii) increase public confidence in the efficacy of a product likely to be mandated or intended for widespread use, and (iii) not doing so will have the opposite result and create uncertainties regarding the efficacy of and need for the COVID-19 vaccines.

VI. Petitioner hereby incorporates the grounds, facts, arguments and opinions stated in the "PETITION FOR ADMINISTRATIVE ACTION REGARDING CONFIRMATION OF EFFICACY END POINTS OF THE PHASE III CLINICAL TRIALS OF COVID-19 VACCINES" which has been submitted to the FDA by Dr. Sin Hang Lee via electronic filing on November 25, 2020 (Exhibit A - Docket No. FDA-2020-P-2225). Exhibit A attached hereto shall be incorporated herein and shall be understood to be a part hereof as though included in the body of this petition.

VII. Petitioner hereby also incorporates the grounds, facts, arguments and opinions stated in the external peer review of the "Drosten-Test" (Exhibit B). Design flaws of certain RT-qPCR tests that are identical to or modeled after what is sometimes called the "Drosten-Test" can lead to false-positive results in trials designed such that PCR results are the primary evidence of infection. Exhibit B attached hereto shall be incorporated herein and shall be understood to be a part hereof as though included in the body of this petition.

VIII. For a vaccine to work, our immune system needs to be stimulated to produce a neutralizing antibody, as opposed to a non-neutralizing antibody. A neutralizing antibody is one that can recognize and bind to some region ('epitope') of the virus, and that subsequently results in the virus either not entering or replicating in your cells. A non-neutralizing antibody is one that can bind to the virus, but for some reason, the antibody fails to neutralize the infectivity of the virus. In some viruses, if a person harbors a non-neutralizing antibody to the virus, a subsequent infection by the virus can cause that person to elicit a more severe reaction to the virus due to the presence of the non-neutralizing antibody. This is not true for all viruses, only particular ones. This is called Antibody Dependent Enhancement (ADE), and is a common problem with Dengue Virus, Ebola Virus, HIV, RSV, and the family of coronaviruses. In fact, this problem of ADE is a major reason why many previous vaccine trials for other coronaviruses failed. Major safety concerns were observed in animal models. If ADE occurs in an individual, their response to the virus can be worse than their response if they had never developed an antibody in the first place. This can cause a hyperinflammatory response, a cytokine storm, and a generally dysregulation of the immune system that allows the virus to cause more damage to our lungs and other organs of our body. In addition, new cell types throughout our body are now susceptible to viral infection due to the additional viral entry pathway. There are many studies that demonstrate that ADE is a persistent problem with coronaviruses in general, and in particular, with SARS-related viruses. ADE has proven to be a serious challenge with coronavirus vaccines, and this is the primary reason many of such vaccines have failed in early in-vitro or animal trials. For example, rhesus macaques who were vaccinated with the Spike protein of the SARS-CoV virus demonstrated severe acute lung injury when challenged with SARS-CoV, while monkeys who were not vaccinated did not. Similarly, mice who were immunized with one of four different SARS-CoV vaccines showed histopathological changes in the lungs with eosinophil infiltration after being challenged with

SARS-CoV virus.

IX. There are some concerning issues with the trial designs, spelled out by Dr. Peter Doshi in the British Medical Journal. Dr. Doshi focuses on the two biggest issues. First, none of the leading vaccine candidate trials is designed to test if the vaccine can reduce severe COVID-19 symptoms, defined as: hospital admissions, ICU or death. And, second, the trials are not designed to test if the vaccine can interrupt transmission (https://www.bmj.com/content/bmj/371/bmj.m4037.full.pdf). If neither of these conditions is met, the vaccine in essence performs like a therapeutic drug, except a vaccine would be taken prophylactically, even by the perfectly healthy, and more than likely carries a higher risk of injury than a therapeutic drug. If this were to be true, then therapeutic drugs would be superior to any COVID vaccine.

X. In the Pfizer/BioNTech mRNA vaccine candidate, polyethylene glycol (PEG) is found in the fatty lipid nanoparticle coating around the mRNA. Seventy percent of people make antibodies to PEG and most do not know it, creating a concerning situation where many could have allergic, potentially deadly, reactions to a PEG-containing vaccine. PEG antibodies may also reduce vaccine effectiveness. Pfizer/BioNTech is also inserting an ingredient derived from a marine invertebrate, mNeonGreen, into its vaccine. The ingredient has bioluminescent qualities, making it attractive for medical imaging purposes, but it is unclear why an injected vaccine would need to have that quality. mNeonGreen has unknown antigenicity.

XI. Several vaccine candidates are expected to induce the formation of humoral antibodies against spike proteins of SARS-CoV-2. Syncytin-1 (see Gallaher, B., "Response to nCoV2019 Against Backdrop of Endogenous Retroviruses" - http://virological.org/t/response-to-ncov2019-against-backdrop-of-endogenous-retroviruses/396), which is derived from human endogenous retroviruses (HERV) and is responsible for the development of a placenta in mammals and humans and is therefore an essential prerequisite for a successful pregnancy, is also found in homologous form in the spike proteins of SARS viruses. There is no indication whether antibodies against spike proteins of SARS viruses would also act like anti-Syncytin-1 antibodies. However, if this were to be the case this would then also prevent the formation of a placenta which would result in vaccinated women essentially becoming infertile. To my knowledge, Pfizer/BioNTech has yet to release any samples of written materials provided to patients, so it is unclear what, if any, information regarding (potential) fertility-specific risks caused by antibodies is included.

According to section 10.4.2 of the Pfizer/BioNTech trial protocol, a woman of childbearing potential (WOCBP) is eligible to participate if she is not pregnant or breastfeeding, and is using an acceptable contraceptive method as described in the trial protocol during the intervention period (for a minimum of 28 days after the last dose of study intervention).

This means that it could take a relatively long time before a noticeable number of cases of post-vaccination infertility could be observed.

XII. It appears that Pfizer/BioNTech have not yet released any samples of written materials provided to patients, so it is unclear what, if any, instructions/information patients/subjects were given regarding ADE and PEG-related issues and (potential) fertility- or pregnancy-specific issues.

D. STAY URGENTLY REQUIRED

I. Petitioner any many EU residents/citizens will suffer irreparable harm because once the EMA approves the COVID- 19 vaccine(s) in question, both governments of EU member states and employers in the EU are most likely going to recommend them for widespread use, and hence without the EMA assuring proper safety trials of the vaccines *now*, the Petitioner and others will not have the opportunity to object to receiving the vaccine based on deficient clinical trials *later*.

II. Furthermore, if the vaccines are licensed without an appropriate efficacy review and without improving the accurate determination of primary endpoints, then any potential acceptance or mandate of these vaccines are likely to be based on inaccurate beliefs and data about the vaccines, namely that they will or might stop transmission of the virus from the vaccine recipient to others and/or that it will reduce severe COVID-19 disease and deaths. The trial protocols in question are not currently properly designed to determine whether either of those objectives can be met.

III. This petition is also not frivolous and is being pursued in good faith as it seeks to increase the scientific integrity and reliability of the trials of the COVID-19 vaccines.

IV. Finally, the public interest also weighs strongly in favor of the requested relief because improving the accurate determination of primary endpoints (i) will comport with the best scientific practices, (ii) increase public confidence in the efficacy of a vaccine expected to be mandated or strongly recommended for widespread use, and (iii) not doing so will have the opposite result in that it will create uncertainties regarding the efficacy of and need for the COVID-19 vaccines.

V. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted on my behalf and on behalf of Co-Petitioner Dr. Michael Yeadon:

Dr. med. Wolfgang Wodarg

Exhibit A
Exhibit B

Exhibit A

VIA ELECTRONIC FILING

November 25, 2020

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

PETITION FOR ADMINISTRATIVE :
ACTION REGARDING :
CONFIRMATION OF EFFICACY :
END POINTS OF THE PHASE III : Docket No. FDA-2020-P-2225
CLINICAL TRIALS OF COVID-19 :
VACCINES :

ADMINISTRATIVE STAY OF ACTION

This petition for a stay of action is submitted on behalf of Dr. Sin Hang Lee ("**Petitioner**") pursuant to 21 C.F.R. § 10.35 and related and relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request the Commissioner of Food and Drugs (the "**Commissioner**") stay the Phase III trials of BNT162b (NCT04368728) to conform with the requests in the "Action Requested" section below.

Because of the compelling need to ensure the safety and efficacy of any COVID-19 vaccine licensed by the FDA, and to allow Petitioner the opportunity to seek emergency judicial relief should the Commissioner deny its Petition, **Petitioner respectfully requests that FDA act on the instant Petition by December 11, 2020.**

A. DECISION INVOLVED

1. Approval of trial design for Phase III trial of BNT162 (NCT04368728)[1]

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[1] NCT04368728 available at https://www.clinicaltrials.gov/ct2/show/NCT04368728 (last visited November 3, 2020).

B. ACTION REQUESTED

2. Stay the Phase III trial of BNT162 (NCT04368728) until its study design is amended to provide that:

> Before an EUA or unrestricted license is issued for the Pfizer vaccine, or for other vaccines for which PCR results are the primary evidence of infection, all "endpoints" or COVID-19 cases used to determine vaccine efficacy in the Phase 3 or 2/3 trials should have their infection status confirmed by Sanger sequencing, given the high cycle thresholds used in some trials. High cycle thresholds, or Ct values, in RT-qPCR test results have been widely acknowledged to lead to false positives.[2]
>
> All RT-qPCR-positive test results used to categorize patient as "COVID-19 cases" and used to qualify the trial's endpoints should be verified by Sanger sequencing to confirm that the tested samples in fact contain a unique SARS-CoV-2 genomic RNA. Congruent with FDA requirements for a confirmed diagnosis of human papillomavirus (HPV) using PCR, the sequencing electropherogram must show a minimum of 100 contiguous bases matching the reference sequence with an Expected Value (E Value) $<10^{-30}$ for the specific SARS-CoV-2 gene sequence based on a BLAST search of the GenBank database (aka NCBI Nucleotide database).

C. STATEMENT OF GROUNDS

3. As detailed herein, (i) without the requested stay, the Petitioner will suffer irreparable harm, (ii) the request is not frivolous and is being pursued in good faith, (iii) the request demonstrates sound public policy, and (iv) the public interest favors granting a stay. [3]

4. The current study designs for the Phase II/III trials of BNT162b ("**the Pfizer Vaccine**") are inadequate to accurately assess efficacy.

5. Petitioner and the public will suffer irreparable harm if the actions requested herein are not granted, because once the FDA licenses this COVID-19 vaccine, both governments and employers may make this product mandatory (in general, or for airline or international travel) or may recommend it for widespread use. If the assignment of cases and non-cases during the course of the trial is not accurate, the vaccine will not have been properly tested. If the vaccine is not

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[2] *See* New York Times. Your Coronavirus Test Is Positive. Maybe It Shouldn't Be. By Apoorva Mandavilli. Published Aug. 29, 2020 and updated Sept. 17, 2020, available at https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html.

[3] The Petitioner hereby incorporates by reference as if fully set forth herein the Statement of Grounds from its Citizen's Petition, dated November 23, 2020, available at, https://beta.regulations.gov/document/FDA-2020-P-2225 (last visited November 25, 2020).

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properly tested, important public policy decisions regarding its use will be based on misleading evidence. The medical and economic consequences to the nation could hardly be higher.

6. The New York State Bar Association has already issued a report on COVID-19 recommending that, "a vaccine subject to scientific evidence of safety and efficacy be made widely available, and widely encouraged, and if the public health authorities conclude necessary, required..."[4] Thus, it is reasonable to suspect that COVID-19 vaccines, including the Pfizer vaccine, could become mandatory. Without the FDA assuring proper efficacy trials of the vaccine now, the Petitioner and the public may not have the opportunity to object to receiving the vaccine, which was approved based on currently deficient and unreliable clinical trial data.

7. Furthermore, if the vaccine is approved without an appropriate and accurate review of efficacy, then any potential acceptance or mandate of these vaccines is likely to be based on inaccurate evidence regarding the vaccine, namely that it will stop transmission of the virus from the vaccine recipient to others and/or that it will reduce severe COVID-19 disease and deaths. The Pfizer trial protocol is currently not designed to determine whether either of those objectives can be met; and even if it was, if cases cannot be reliably identified, neither objective could be reliably met.

8. The public interest also weighs strongly in favor of the requested relief because improving the accurate determination of primary endpoints (i) will comport with the best scientific practices, (ii) increase public confidence in the efficacy of a product likely to be mandated or intended for widespread use, and (iii) not doing so will have the opposite result and create uncertainties regarding the efficacy of and need for the COVID-19 vaccines.

7. According to the trial protocol, "8.1. Efficacy and/or Immunogenicity Assessments," the trial's primary endpoint is prevention of symptomatic disease in vaccine recipients. In order to evaluate that endpoint, the trial will track recorded COVID-19 disease. The definition of confirmed COVID-19 is:

> presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):
>
> - Fever;
> - New or increased cough;
> - New or increased shortness of breath;
> - Chills;
> - New or increased muscle pain;
> - New loss of taste or smell;
> - Sore throat;
> - Diarrhea;
> - Vomiting.

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[4] https://nysba.org/app/uploads/2020/06/2b-REV-6-12-20-FINAL-HOD-RESOLUTIONS-1-through-4.pdf.

8. As a result, if a participant has a positive reverse transcription-quantitative polymerase chain reaction (**"RT-qPCR"**) test along with a cough or sore throat, that participant would be considered as a "confirmed COVID-19 case" and would be counted as an endpoint. Once a trial reaches a certain number of "endpoints", the trial is closer to seeking FDA approval or licensure by demonstrating that the vaccine is "effective" (in that the vaccine group had lower incidence of endpoints than the control group).

9. This effectively means that the efficacy of the vaccine will be determined based on only symptoms of non-specific disease in conjunction with a PCR positive laboratory test.

10. According to the trial protocol, "8.1 Efficacy and/or Immunogenicity Assessments," efficacy will be assessed throughout a participant's involvement in the study through surveillance for potential cases of COVID-19. If, at any time, a participant develops acute respiratory illness (see Section 8.13), for the purposes of the study he or she will be considered to potentially have COVID-19 illness. In this circumstance, the participant should contact the site, an in-person or telehealth visit should occur, and assessments should be conducted as specified in the SoA. The assessments will include a nasal (midturbinate) swab, which will be tested at a central laboratory using a reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; FDA approved under EUA), or other equivalent nucleic acid amplification–based test (ie, NAAT), to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests (as detailed in Section 8.13) will be assessed. The central laboratory NAAT result will be used for the case definition, unless no result is available from the central laboratory, in which case a local NAAT result may be used if it was obtained using 1 of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2
- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)
- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001)

11. These test kits referred to in the trial protocol, namely the Cepheid Xpert Xpress SARS-CoV-2, the Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), and the Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001), are very unreliable tools when they are used to determine whether the nasal swab sample collected from a symptomatic participant contains SARS-CoV-2 or not. These real-time RT-PCR or RT-quantitative PCR tests should be referred to as rRT-PCR or RT-qPCR tests to be distinguished from conventional RT-PCR. The very short RT-qPCR product (amplicon) cannot be analyzed by automated Sanger sequencing as the products of conventional PCR can. And DNA sequencing for validation of the PCR products is needed to correctly determine if the presumptive RT-qPCR-positive SARS-CoV-2 test result is a true positive or a false positive. The reasoning is further outlined as follows:

a. Nowadays DNA sequencing of the PCR amplicon of the genomic nucleic acid of the pathogen is a universally accepted technology for detection and for confirmation of infectious agents, especially pathogenic viruses, in clinical specimens. On January 10,

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2020, the first SARS-CoV-2 genome sequence was released online. On the same day, a group of American scientists, most from the CDC, immediately designed 2 complementary panels of primers to amplify the virus genome for sequencing. The PCR amplicons averaged 550 bp in size in their research.[5]

b. The World Health Organization (WHO) guidance titled "WHO Laboratory testing for coronavirus disease (COVID-19) in suspected human cases-Interim guidance dated 19 March 2020" advised "Routine confirmation of cases of COVID-19 is based on detection of unique sequences of virus RNA by NAAT such as real-time reverse transcription-polymerase chain reaction (rRT-PCR) with confirmation by nucleic acid sequencing when necessary."[6]

c. The FDA also recognizes the inherent inaccuracy of the RT-qPCR tests. In its letter issued on February 4, 2020 authorizing emergency use of the CDC 2019-Novel Coronavirus (2019-nCoV, renamed as SARS-CoV-2) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel, the FDA specifically stated that the test panel is "for the ***presumptive*** qualitative detection of nucleic acid from the 2019-nCoV (sic) in upper and lower respiratory specimens."[7]

d. In addition to false-negative results, these RT-qPCR test kits under EUA also generate false-positive test results. For example, 77 positive SARS-CoV-2 test results on a group of football players all turned out to be false positives on repeat tests.[8]

e. The FDA has officially alerted clinical laboratory staff and health care providers of an increased risk of false-positive results with some of these commercial test kits permitted to be used under EUA.[9]

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[5] Paden CR, Tao Y, Queen K, Zhang J, Li Y, Uehara A, Tong S. Rapid, Sensitive, Full-Genome Sequencing of Severe Acute Respiratory Syndrome Coronavirus 2. Emerg Infect Dis. 2020 Oct;26(10):2401-2405. doi: 10.3201/eid2610.201800. Epub 2020 Jul 1. PMID: 32610037; PMCID: PMC7510745.

[6] WHO Laboratory testing for coronavirus disease (COVID-19) in suspected human cases-Interim guidance 19 March 2020. Available from: https://www.who.int/publications/i/item/10665-331501.

[7] FDA letter dated February 4, 2020 authorizing emergency use of the CDC 2019-Novel Coronavirus (2019-nCoV, renamed as SARS-CoV-2) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel. See Open letter from FDA to Robert R. Redfield, MD, Director, Centers for Disease Control and Prevention. March 15, 2020. https://www.fda.gov/media/134919/download.

[8] Kevin Patra. Around the NFL- All 77 false-positive COVID-19 tests come back negative upon reruns. Aug 24, 2020. Available from: https://www.nfl.com/news/all-77-false-positive-covid-19-tests-come-back-negative-upon-reruns.

[9] FDA. False Positive Results with BD SARS-CoV-2 Reagents for the BD Max System - Letter to Clinical Laboratory Staff and Health Care Providers. Available from: https://www.fda.gov/medical-devices/letters-health-care-providers/false-positive-results-bd-sars-cov-2-reagents-bd-max-system-letter-clinical-laboratory-staff-and Accessed November 2, 2020; *see also* FDA. Risk of Inaccurate Results with Thermo Fisher Scientific TaqPath COVID-19 Combo Kit - Letter to Clinical Laboratory Staff and Health Care Providers. Available from: https://www.fda.gov/medical-devices/letters-health-care-providers/risk-inaccurate-results-thermo-fisher-scientific-taqpath-covid-19-combo-kit-letter-clinical?utm_campaign=2020-08-17%20Risk%20of%20Inaccurate%20Results%20with%20Thermo%20Fisher%20Scientific%20TaqPath&utm_medium=email&utm_source=Eloqua.

f. To resolve the problems caused by these inherently inaccurate tests, the FDA's position is that false results can be investigated using an additional EUA RT-qPCR assay, and/or Sanger sequencing.[10] Since an additional EUA RT-qPCR test result may also generate a false result, Sanger sequencing is the *de facto* gold standard for confirmation of presumptive qualitative detection of nucleic acid from the SARS-CoV-2 and for excluding false-positive cases.

g. According to the FDA guidance on molecular diagnosis of viral infection caused by human papillomavirus (HPV), a conventional PCR detection of genomic DNA followed by Sanger sequencing on both strands of the PCR amplicon (bi-directional sequencing) that contains a minimum of 100 contiguous bases is acceptable as valid diagnostics for HPV infection provided the sequence matches the reference or consensus sequence, e.g. with an Expected Value (E Value) $<10^{-30}$ for the specific HPV DNA target based on a BLAST search of the GenBank (NCBI Nucleotide) database.[11] Following this FDA guidance, and showing the feasibility of implementing the FDA guidance for accurate diagnosis of COVID-19, a protocol using the nested PCR cDNA amplicon of a 398-base highly conserved SARS-CoV-2 N gene segment as the template for Sanger sequencing was developed for confirmatory detection of SARS-CoV-2 in clinical samples.[12]

h. DNA sequencing verification is necessary for confirmation of the presumptive SARS-CoV-2-positive cases in the Pfizer vaccine's Phase II/III clinical trial because, according to its Protocol, the specimens collected from the symptomatic trial subjects were sent to a central laboratory using a reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; FDA approved under EUA), or other equivalent nucleic acid amplification–based test (i.e., NAAT), to detect SARS-CoV-2.

In order to raise the detection sensitivity, the mean Ct value of the Cepheid system is set as high as 42.9 for the N2 target, and as high as 44.9 for the E target, as shown in Table 4 of Instructions for Users (Cepheid 302-3562, Rev. E September 2020).[13]

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[10] FDA. Molecular Diagnostic Template for Laboratories. Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Available from: https://www.fda.gov/media/135659/download .

[11] FDA. Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses. Available from: https://www.fda.gov/media/92930/download.

[12] Lee SH. Testing for SARS-CoV-2 in cellular components by routine nested RT-PCR followed by DNA sequencing. International Journal of Geriatrics and Rehabilitation. 2020; 2:69-96. Available from: http://www.int-soc-clin-geriat.com/info/wpcontent/uploads/2020/03/Dr.-Lees-paper-on-testing-for-SARS-CoV-2.pdf.

[13] Cepheid. GeneXpert. Instructions for Users. XPRSARS-COV2-10. 302-3562, Rev. E September 2020 https://www.cepheid.com/Package%20Insert%20Files/Xpress-SARS-CoV-2/Xpert%20Xpress%20SARS-CoV-2%20Assay%20ENGLISH%20Package%20Insert%20302-3562-GX%20Rev.%20E.pdf.

Table 4. LoD Determination using USA-WA1/2020 Strain

Strain	Concentration (PFU/mL)	Total Valid Results	Hit Rate (%)	Hit Rate (%)	Mean Ct	Mean Ct
			N2 Target	E Target	N2 Target	E Target
SARS-CoV-2 virus (USA_WA1/2020)	0.0200	20	100	95.0	38.3	36.4
	0.0050	22	95.5	68.2	40.5	39.1
	0.0025	22	90.9	36.4	41.5	39.6
	0.0010	22	50.0	18.2	42.0	42.0
	0.0005	22	45.5	18.2	41.7	41.5
	0.0003	22	18.2	4.5	42.1	44.9
	0.0001	22	9.1	0	42.9	N/A
	0	0	0	0	N/A	N/A

At Ct values between 36.0 and 44.9, many RT-qPCR positive test results are false positives.

i. The results of the 3 RT-qPCR test kits used in the trial protocol are not comparable. A sample identified as negative by the Abbott kit can be classified as positive by the Cepheid kit. According to an FDA survey, the limit of detection by the Cepheid Xpert Xpress SARS-CoV-2 test kit and the limit of detection by Abbott RealTime SARS-CoV-2 assay kit are found to be identical, namely both being at 5400 NAAT Detectable Units/ mL, as shown in the comparative data extracted from an FDA reference panel.[14]

5400	Cepheid	Xpert Xpress SARS-CoV-2 test
5400	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay

However, due to the designation of higher cycle threshold test results as positives, the Cepheid Xpert kits have classified many Abbott kit negative cases as positives in a head-to-head comparative study as shown in the following "Table 2" extracted from a report by Basu et al.[15]

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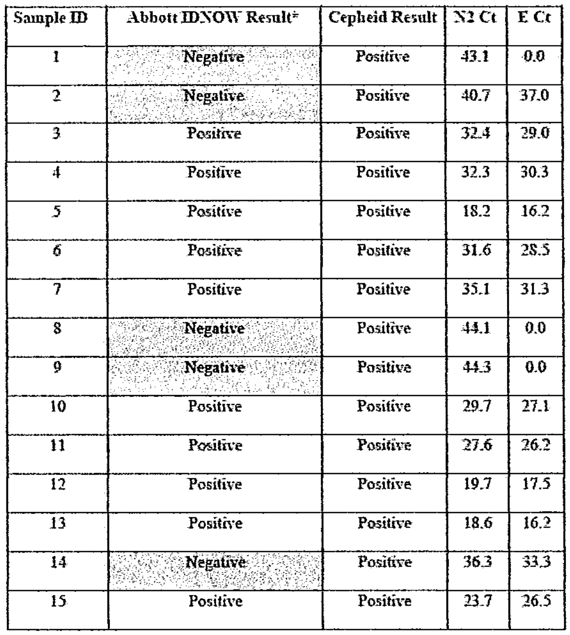
[14] FDA. SARS-CoV-2 Reference Panel Comparative Data. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative- data.

[15] *See* bioRxiv preprint doi: https://doi.org/10.1101/2020.05.11.089896; Basu A, Zinger T, Inglima K, Woo KM, Atie O, Yurasits L, See B, Aguero-Rosenfeld ME. Performance of Abbott ID Now COVID-19 Rapid Nucleic Acid Amplification Test Using Nasopharyngeal Swabs Transported in Viral Transport Media and Dry Nasal Swabs in a New York City Academic Institution. J Clin Microbiol. 2020 Jul 23;58(8):e01136-20. doi: 10.1128/JCM.01136-20. PMID: 32471894; PMCID: PMC7383552.

Table 2. Results of sequential nasopharyngeal specimens submitted in VTM from the Emergency Department tested on both Abbot ID NOW and Cepheid GeneXpert for SARS CoV-2 RNA



Sample ID	Abbott IDNOW Result*	Cepheid Result	N2 Ct	E Ct
1	Negative	Positive	43.1	0.0
2	Negative	Positive	40.7	37.0
3	Positive	Positive	32.4	29.0
4	Positive	Positive	32.3	30.3
5	Positive	Positive	18.2	16.2
6	Positive	Positive	31.6	28.5
7	Positive	Positive	35.1	31.3
8	Negative	Positive	44.1	0.0
9	Negative	Positive	44.3	0.0
10	Positive	Positive	29.7	27.1
11	Positive	Positive	27.6	26.2
12	Positive	Positive	19.7	17.5
13	Positive	Positive	18.6	16.2
14	Negative	Positive	36.3	33.3
15	Positive	Positive	23.7	26.5

j. One of the Cepheid Xpert kit users has put out an alert, stating "The instruments are presently set by the manufacturer to interpret a single target positive with very poor amplification efficiency (high Cycle Threshold [Ct] and/or atypical curve) as 'DETECTED.' None of these to date have confirmed positive when tested on other systems using similar targets, and may be a false positive due to background noise."[16]

k. Another group of users also found that some tested samples classified as positives by the Cepheid test kits cannot be confirmed with other test kits. These authors published a report, stating: "We found that the sensitivity of the Xpert Xpress SARS-CoV-2 assay was 100% (20 of 20) and the specificity was 80% (16 of 20). When looking at the cycle threshold (Ct) values from the GeneXpert assay we observed that specimens with no amplification of the *E* gene (ie, Ct=0) and Ct values for the *N2* gene greater than 40 cycles were considered as positives, whereas they were negative using the other RT-PCR system (Da An Gene)."[17]

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[16] Diagnostic Laboratory Services Inc. Technical Alert. Cepheid GeneXpert and BD Max Instruments may be Reporting False Positives. https://dlslab.com/documents/bulletins/2020/tech-memo-sars-cov-2-pcr-possible-false-positive-6-19-2020.pdf.

[17] Rakotosamimanana N, Randrianirina F, Randremanana R, Raherison MS, Rasolofo V, Solofomalala GD, Spiegel A, Heraud JM. GeneXpert for the diagnosis of COVID-19 in LMICs. Lancet Glob Health. 2020 Oct 19:S2214-109X(20)30428-9. doi: 10.1016/S2214-109X(20)30428-9. Epub ahead of print. PMID: 33091372; PMCID: PMC7572106.

12. DNA sequencing verification of the RT-qPCR positive test results is absolutely necessary in this placebo-controlled randomized clinical trial because *de facto* unblinding has occurred among the participants. According to the trial protocol Section 8.13. COVID-19 Surveillance (All Participants), "If a participant experiences any of the following (irrespective of perceived etiology or clinical significance), he or she is instructed to contact the site immediately and, if confirmed, participate in an in-person or telehealth visit as soon as possible." This contact would trigger an automatic NAAT test by a Cepheid RT-qPCR assay at the central laboratory or at a local laboratory by any similar acceptable methods.

At the time of enrollment, the participants were informed that each of them would be injected with a vaccine to protect against COVID-19 infection or a saline placebo without disclosing which one of the two was injected into the participant. However, all participants were also informed that the vaccine may cause the following reactions:

- Fever ≥39.0°C (≥102.1°F).
- Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
- Severe pain at the injection site.
- Any severe systemic event.

It is commonly known to the general public and especially to the informed clinical trial participants that intramuscular injection of a very small amount of sterile normal saline will not cause fever, local redness and swelling, and severe pain, or systemic reactions. The participants receiving placebo would intuitively or reasonably know that they were not injected with a vaccine and were not protected against COVID-19 disease due to the lack of any vaccine reaction after the injection. As a result, more participants receiving placebo than those receiving vaccine would report to the "site" manager when they developed any minor symptoms, such as a sore throat or a new cough for the fear of coming down with COVID-19. The site manager must investigate the symptoms reported, including ordering a RT-qPCR test by Cepheid assay to be performed at the Central Laboratory according to Protocol. The more severe cases might be tested locally by Abbott kits or Roche kits because they might have to be tested in the hospital after admission, and because many hospitals are aware of the high false positive rates generated by the Cepheid kits. The results generated by these test kits are not comparable since the Cepheid test kits using a very high Ct value up to 44.9 for "detection of SARS-CoV-2 genomic RNA" **tend to generate many more false positives than the other test kits**. A higher number of false-positive test results in the participants receiving placebo will artificially raise the efficacy of the vaccine, unless the RT-qPCR test results are verified by nucleotide sequencing to eliminate all false-positive test results.

13. Based on an MPR report published on November 8, 2020, there are only 180 confirmed cases of COVID-19 in this clinical trial series that have been analyzed to support the vaccine efficacy evaluation.[18] If the Sponsor (BioNTech/Pfizer) is unable to perform confirmatory Sanger sequencing tests on these 180 RNA extract residual samples, the Petitioner hereby offers

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[18] Diana Ernst, RPh. Final Analysis Reveals COVID-19 Vaccine Candidate BNT162b2 95% Effective. MPR Report. November 18, 2020. https://www.empr.com/home/news/drugs-in-the-pipeline/pfizer-biontech-mrna-based-vaccine-bnt162b2-against-covid19-effective/.

to re-test them immediately with Sanger sequencing[19] and submit the laboratory data to support FDA's evaluation. Therefore, there is no excuse for the Sponsor to refuse using the gold standard Sanger sequencing technology for endpoint validation.

14. In summary, based on the scientific data available in the public domain and the FDA guidance, all RT-qPCR test results for detection of SARS-CoV-2 gene sequence must be considered presumptive. The Cepheid test kits for SARS-CoV-2 are known to generate more false-positive test results than other EUA assay kits.

15. The residues of the tested samples that were classified as positive for SARS-CoV-2 by the Cepheid GeneXpert assay, or equivalent as stated in the Pfizer Clinical Trial Protocol, must be re-tested by a Sanger sequencing method to confirm that the presumptive positive samples in fact contain a unique sequence of SARS-CoV-2 genome. Only then can the positive test results from the Cepheid GeneXpert test kits be accepted as an accurate component of the "endpoint." Only then can one nonspecific symptom plus laboratory positivity be accepted as a valid measure of confirmed COVID-19 cases or "endpoints."

Stay Urgently Required

16. Petitioner will suffer irreparable harm because once the FDA licenses this COVID-19 vaccine, states are expected to make this product mandatory, and hence without the FDA assuring proper safety trials of the vaccine *now*, the Petitioner will not have the opportunity to object to receiving the vaccine based on deficient clinical trials *later*.

17. For example, the New York State Bar Association recently passed a resolution recommending that "[s]hould the level of immunity be deemed insufficient by expert medical and scientific consensus to check the spread of COVID-19 and reduce morbidity and mortality, **a mandate and state action should be considered.**"[20] Mandating administration of the vaccine, thereby eliminating the right to informed consent, makes acute the need to assure that the safety and efficacy of any COVID-19 vaccine is robustly studied in an adequate clinical trial monitoring for any potential adverse events.

18. Furthermore, if the vaccine is licensed without an appropriate efficacy review and without improving the accurate determination of primary endpoints, then any potential acceptance or mandate of these vaccines are likely to be based on inaccurate beliefs about the vaccine, namely that it will stop transmission of the virus from the vaccine recipient to others or that it will reduce severe COVID-19 disease and deaths. The trial protocols are not currently designed to determine whether either of those objectives can be met.

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[19] Lee SH. Testing for SARS-CoV-2 in cellular components by routine nested RT-PCR followed by DNA sequencing. International Journal of Geriatrics and Rehabilitation. 2020; 2:69-96. Available from: http://www.int-soc-clin-geriat.com/info/wpcontent/uploads/2020/03/Dr.-Lees-paper-on-testing-for-SARS-CoV-2.pdf.

[20] https://nysba.org/app/uploads/2020/11/11.-Health-Law-Section-COVID-19-Report-September-20-2020-with-all-comments.pdf (emphasis added) (last visited November 10, 2020).

19. This request is also not frivolous and is being pursued in good faith as it seeks to increase the scientific integrity and reliability of the trials of the COVID-19 Vaccines.

20. Finally, the public interest also weighs strongly in favor of the requested relief because improving the accurate determination of primary endpoints (i) will comport with the best scientific practices, (ii) increase public confidence in the efficacy of a product expected to be mandated, and (iii) not doing so will have the opposite result in that it will create uncertainties regarding the efficacy of and need for the COVID-19 Vaccines.

21. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted,

Sin Hang Lee

Dr. Sin Hang Lee

Exhibit B

Review Report by an International Consortium of Scientists in Life Sciences (ICSLS) - Corman-Drosten *et al.*, Eurosurveillance 2020 (Updated: 29.11.2020)

External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results.

Pieter Borger(1 *), Bobby Rajesh Malhotra(2) , Michael Yeadon(3) , Clare Craig(4)
Kevin McKernan(5) , Klaus Steger(6) , Paul McSheehy(7) , Lidiya Angelova(8)
Fabio Franchi(9), Thomas Binder(10), Henrik Ullrich(11) , Makoto Ohashi(12)
Stefano Scoglio(13), Marjolein Doesburg-van Kleffens(14), Dorothea Gilbert(15)
Rainer Klement(16), Ruth Schruefer(17), Berber W. Pieksma(18), Jan Bonte(19)
Bruno H. Dalle Carbonare(20), Kevin P. Corbett(21), Ulrike Kämmerer(22)

* Corresponding Author

ABSTRACT

"In the publication entitled "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR" (Eurosurveillance 25(8) 2020) the authors present a diagnostic workflow and RT-qPCR protocol for detection and diagnostics of 2019-nCoV (now known as SARS-CoV-2), which they claim to be validated, as well as being a robust diagnostic methodology for use in public-health laboratory settings.

In light of all the consequences resulting from this very publication for societies worldwide, a group of independent researchers performed a point-by-point review of the aforesaid publication in which 1) all components of the presented test design were cross checked, 2) the RT-qPCR protocol-recommendations were assessed with respect to good laboratory practice, and 3) parameters examined against relevant scientific literature covering the field.

The published RT-qPCR protocol for detection and diagnostics of 2019-nCoV and the manuscript suffer from numerous technical and scientific errors, including insufficient primer design, a problematic and insufficient RT-qPCR protocol, and the absence of an accurate test validation. Neither the presented test nor the manuscript itself fulfils the requirements for an acceptable scientific publication. Further, serious conflicts of interest of the authors are not mentioned. Finally, the very short timescale between submission and acceptance of the publication (24 hours) signifies that a systematic peer review process was either not performed here, or of problematic poor quality.

We provide compelling evidence of several scientific inadequacies, errors and flaws. Considering the scientific and methodological blemishes presented here, we are confident that the editorial board of Eurosurveillance has no other choice but to retract the publication."

Review Report by an International Consortium of Scientists in Life Sciences (ICSLS) - Corman-Drosten *et al.*, Eurosurveillance 2020 (Updated: 29.11.2020)

CONCISE REVIEW REPORT

This paper will show numerous serious flaws in the Corman-Drosten paper, the significance of which has led to worldwide misdiagnosis of infections attributed to SARS-CoV-2 and associated with the disease COVID-19. We are confronted with stringent lockdowns which have destroyed many people's lives and livelihoods, limited access to education and these imposed restrictions by governments around the world are a direct attack on people's basic rights and their personal freedoms, resulting in collateral damage for entire economies on a global scale.

There are ten fatal problems with the Corman-Drosten paper which we will outline and explain in greater detail in the following sections.

The first and major issue is that the novel Coronavirus SARS-CoV-2 (in the publication named 2019-nCoV and in February 2020 named SARS-CoV-2 by an international consortium of virus experts) is based on in silico (theoretical) sequences, supplied by a laboratory in China [1], because at the time neither control material of infectious ("live") or inactivated SARS-CoV-2 nor isolated genomic RNA of the virus was available to the authors. To date no validation has been performed by the authorship based on isolated SARS-CoV-2 viruses or full length RNA thereof. According to Corman et al.:

> *"We aimed to develop and deploy robust diagnostic methodology for use in public health laboratory settings without having virus material available."* [1]

The focus here should be placed upon the two stated aims: a) *development* and b) *deployment of a diagnostic test for use in public health laboratory settings.* These aims are not achievable without having any actual virus material available (e.g. for determining the infectious viral load). In any case, only a protocol with maximal accuracy can be the mandatory and primary goal in any scenario-outcome of this magnitude. Critical viral load determination is mandatory information, and it is in Christian Drosten's group responsibility to perform these experiments and provide the crucial data.

Nevertheless these in silico sequences were used to develop a RT-PCR test methodology to identify the aforesaid virus. This model was based on the assumption that the novel virus is very similar to SARS-CoV from 2003 as both are beta-coronaviruses.

The PCR test was therefore designed using the genomic sequence of SARS-CoV as a control material for the Sarbeco component; we know this from our personal email-communication with [2] one of the co-authors of the Corman-Drosten paper. This method to model SARS-CoV-2 was described in the Corman-Drosten paper as follows:

> *"the establishment and validation of a diagnostic workflow for 2019-nCoV screening and specific confirmation, designed in absence of available virus isolates or original*

2021

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www.medicosporlaverdad.net

Biólogos por La Verdad.
www.biologosporlaverdad.es

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por la verdad

[JUSTIFICACIÓN]

En el presente documento, firmado por 60 médicos y 36 biólogos, se presentan argumentos de peso avalados por estudios científicos previos y reportes de casos reales sobre muertes y efectos adversos registrados a las agencias del medicamento de todo el mundo; información empírica y objetiva en la que los abajo firmantes nos respaldamos, para pedir el CESE INMEDIATO DE LAS CAMPAÑAS DE VACUNACIÓN *destinadas a implementar productos génicos en la población sana, con la excusa del virus SARS CoV 2. Creemos firmemente que los riesgos no son asumibles, ni un solo efecto adverso o muerte debe ser tolerado. Entendemos que es imprescindible demostrar sin ningún lugar a dudas, el aislamiento del virus SARS CoV 2, su cultivo directo de pacientes con RT PCRs positivas, para asegurar al 100% su presencia y demostrar su conexión directa con la enfermedad denominada COVID 19, antes de exponer a la población a cualquier ensayo clínico. Consideramos una absoluta barbaridad la experimentación con productos génicos en las personas sanas, ya que supone un ataque directo al código deontológico de nuestra profesión, la cuál se fundamenta en la preservación de la salud y la vida.*

21/marzo 2021

Ha sido aceptado por las instituciones (OMS) y por los gobiernos, en base a un paradigma biológico obsoleto y reduccionista, que el llamado síndrome COVID-19 está producido por un virus denominado SARS-CoV-2, el cual no ha sido aislado y purificado de forma objetiva según reconocen los principales estamentos académicos. **(1)**

El síndrome COVID-19 no es una entidad nosológica desconocida en medicina, ya que tiene las características clínicas y biológicas de los síndromes hemofagocíticos o de inmunidad alterada que, si bien, pueden estar **desencadenados** (lo cual no es lo mismo que causados) por infecciones víricas o bacterianas, es preciso que confluyan diversas condiciones fisiopatológicas e inmunopatológicas previas, para su desarrollo y manifestación clínica, entre las que se encuentran tóxicos y vacunas, particularmente la vacunación y revacunación antigripal **(2,3,4)**

Como única solución para la pandemia de COVID-19, declarada por la OMS, se ha propuesto, sin tener en cuenta otras opciones de tratamiento, tanto convencionales como alternativas **(5)** una vacunación universal para la que se han desarrollado, a marchas forzadas y sin las suficientes garantías de eficacia y seguridad, **una serie de fármacos de terapia génica** que no cumplen los requisitos biológicos de las vacunas, aunque se intenten equiparar con las mismas. La actual aprobación de las llamadas "vacunas covid" por la FDA y por la EMA es **condicionada y para uso de emergencia,** estando todavía en fase **EXPERIMENTAL:** fase IV o de estudio postcomercialización, habiéndose desarrollado en un tiempo record, **ya que se han superpuesto las fases I y II de los estudios** con voluntarios. Se argumenta que esta rapidez en la comercialización de dichas vacunas ha sido posible gracias a la colaboración internacional y a la gran inversión económica realizada por estados e instituciones, pero **EL TIEMPO NECESARIO** para realizar los estudios de eficacia y seguridad no se puede acortar por estos motivos **(6).** Además, no es lo mismo producir un fármaco para estudio en voluntarios, que fabricarlo **DE MANERA INDUSTRIAL** para uso en millones de personas y de forma acelerada. Esto conlleva problemas de logística que las empresas no sabemos si han resuelto de manera adecuada, complicando aún más los riesgos derivados de la falta de seguridad **(7).**

Están en fase de desarrollo y / o comercialización, una serie de vacunas tanto convencionales como experimentales (GÉNICAS) que supondrán enormes beneficios para la Industria Farmacéutica (es notable que MERCK, empresa líder y con la mayor experiencia en la fabricación de vacunas, se haya quedado al margen de esta carrera).

Hay actualmente cuatro tipos de vacunas: dos convencionales y dos nunca antes probadas ni aprobadas (génicas).

A nuestro juicio, las que ofrecen más dudas son las **NUEVAS VACUNAS GÉNICAS** , en realidad son más bien fármacos para tratamiento génico, ya que no entran en la definición y comportamiento biológico de lo que se supone es una vacuna. De estas hay, a su vez, dos tipos:

I.-VACUNAS DE ARN ENCAPSULADO: (Pfizer, Moderna y Cure Vac):

Las nuevas vacunas de ARNm con nucleósidos modificados contienen N^1-metilpseudouridina en lugar de uridina y codifican un péptido optimizado (P2-mutado) de longitud completa de la Glicoproteína S encapsulada en nanopartículas lipídicas (LNP) que contienen polietilenglicol y colesterol.

El BNT162b2 LNP de Pfizer, también contiene ALC- 0315 (4-hidroxibutil) azanedil) bis (hexano-6,1-diil)bis(2-hexildecanoato) y ALC-0159 (2[(polietilenglicol)-2000]-N,N-ditetradecilacetamida), 1,2-Distearoil-sn-glicero-3 fosfocolina, DSPC . Colesterol, cloruro de potasio, dihidrógenofosfato de potasio, cloruro sódico, fosfato disódico dihidratado, sucrosa y agua para inyección **(8).**

El LNP de Moderna ARNm 1273 contiene SM-102 (8 - (2-hidroxietil) (6-oxo-6- (undeciloxi) hexil) amino) octanoato de heptadecan-9-ilo) y 1,2-dimiristoil-rac-glicero-3-metoxipolietilenglicol-2000 (PEG) .

La vacuna BioNTech se administra por vía intramuscular (IM) en dos dosis de 30 µg con 21 días de diferencia, el producto Moderna en dos dosis de 100 µg IM con 28 días de diferencia.

Es de destacar que en los ensayos clínicos en fase 1 de BioNTech (para valorar dosis-eficacia) se comprobó la misma eficacia (producción de anticuerpos) con 10 microg que con 30 microg de ARN. Pero la toxicidad aumentaba con el aumento de la cantidad de ARN. A pesar de ello se decidió seleccionar la dosis más alta y administrar también una segunda dosis.**(9).**

En cuanto al ARNm de Moderna hay que señalar que es una dosis muy alta (100 microg), por lo que inducirá mayor toxicidad.

Otros dos tipos de vacunas de ARNm sintético LNP COVID-19 también han entrado en pruebas: CureVac acaba de iniciar un ensayo de fase 2/3 para su producto de ARNm deficiente en uridina sin modificar (CVnCoV), y durante el verano Arcturus Therapeutics e Imperial College London comenzaron el ensayo en fase 1 **de vacunas de ARN autoamplificadoras (10)** basadas en un alfavirus que codifica proteínas no estructurales para replicar el inmunógeno de proteína S.

Las actualmente comercializadas (Pfizer y Moderna) consisten en moléculas de ARNm modificado (se ha cambiado un nucleósido o elemento constituyente del ARN, la uridina, por una metil-pseudouridina), envueltas en cápsulas nanolipídicas constituidas por lípidos neutros (polietilenglicol) y lípidos catiónicos de elevada toxicidad **(9)**.

Este ARNm contiene la secuencia genómica capaz de codificar un análogo de la Spike protein del SARS-CoV-2, por lo que se supone que, una vez dentro de la célula, utilizará la maquinaria celular (ribosomas) para traducir la secuencia de bases de dicho ARN a la secuencia de aminoácidos de la proteína S, dicha proteína o más bien fracciones de la misma, serán expuestas en la membrana celular junto a moléculas del MHC para ser reconocidas como antígenos por las células inmunes que desarrollarán una respuesta de anticuerpos frente a los mismos, pero también de Linfocitos T.

De manera que, si ya existen linfocitos T8 citotóxicos por infecciones anteriores por otros coronavirus, lo cual es frecuente, o en una segunda exposición, se producirá un ataque con destrucción y muerte de aquellas células que expresen en su membrana los antígenos derivados de la proteína S vacunal. Esto afectará a las células musculares, en el lugar de la inyección, pero también puede afectar a otras células, particularmente células inmunes y endotelios vasculares. **(11)**

Es importante destacar al respecto, la estructura tridimensional de la Spike protein que es de tipo cuaternario, estando formada por diversas subunidades, algunas de las cuales tienen homologías de secuencia importantes con proteínas endógenas, lo que es conocido en ciencia como epitopos inseguros **(12)**, por lo que no se puede descartar que se produzca reacción inmune cruzada, lo que daría lugar a procesos y enfermedades autoinmunes.

El proceso de inmunización protectora descrito por los fabricantes, es una suposición teórica simplificada de las acciones que el ARN alterado, introducido en un organismo por vía parenteral puede hacer y hará.

Enumeramos otras posibilidades concomitantes y/o alternativas, así como los posibles riesgos no tenidos en cuenta:

1°) Distribución del ARN vacunal:

Al ser inoculado por vía parenteral, el ARN vacunal se distribuirá por todo el organismo, como se ha comprobado experimentalmente, pudiendo entrar en las células endoteliales vasculares y en las células inmunes (leucocitos y linfocitos) y particularmente en células hepáticas e incluso nerviosas puesto que las partículas nanolipídicas le permiten atravesar la barrera hematoencefálica **(13)**y es conocido también que la spike protein juega un papel en la neuroinmunopatología (Desforges et al 2014; Lyons-Weiler 2020). Por estas razones todas estas células y los órganos que forman pueden ser dañados.

2°) Homologías de secuencia del ARN vacunal (Epitopos inseguros):

La Spike protein del SARS-CoV-2 es una proteína de fusión de tipo 1 similar a la de otros virus como el VIH y virus influenza **(14)** y tiene homologías de secuencia importantes con proteínas de fusión codificadas por HERVs (retrovirus endógenos que forman parte de nuestro genoma donde cumplen importantes funciones). Concretamente la subunidad de fusión S2, pero también la subunidad de unión S1, de cada trímero de la Spike protein, tiene homología con la Sincitina 1 (Syn-1) del HERV-W codificado en el cromosoma 7 del genoma humano **(15)**. Esta proteína Syn-1 es imprescindible para la formación adecuada de la placenta humana y, por tanto para un normal desarrollo de la gestación. Pero también es necesaria para la unión del espermatozoide con el óvulo, por lo que es imprescindible para la fecundación **(15)**. Como consecuencia de la analogía de la Spike protein y la Syn-1 se puede producir una reacción cruzada de anticuerpos contra las sincitinas y **provocarse abortos e infertilidad femenina.** Esto podría ocurrir en el proceso de formación y exposición celular de subunidades de la Spike protein o durante su proteólisis metabólica. Por otra parte ya se ha podido comprobar la producción de abortos como reacción adversa a estas vacunas de ARN **(16)**.

3°) La Spike protein del SARS-CoV-2 tiene también homologías de secuencia con la proteína sincitina 2 (Syn-2) codificada por HERV-FRD en el cromosoma 6 del genoma humano. La Sincitina 2, además de intervenir en la formación de la placenta, posee actividad inmunosupresora con la que consigue hacer invisible el feto ante el sistema inmune de la madre, con lo cual se impide el rechazo alogénico y la muerte fetal. Por esta razón, una posible reacción cruzada de anticuerpos hacia la spike protein, que afectara a la Sincitina 2, podría provocar el rechazo inmune materno del feto, además

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de otros efectos colaterales no deseados como parte de esta previsible inmunidad cruzada. De hecho ya se ha comprobado la **muerte de nonatos** tras la vacunación covid materna **(17) (18).**

4°) Posible comportamiento como patógeno sintético del ARN vacunal:

Está descrito en la literatura científica el fenómeno por el cual determinadas infecciones víricas desencadenan la expresión de proteínas HERVs (por ejemplo virus de la influenza A)**(19).** También se ha documentado la mayor morbimortalidad por COVID GRAVE en personas vacunadas de la gripe (influenza) en todo el mundo **(3),** por lo que nos planteamos que, determinadas infecciones y antígenos vacunales, pueden producir modificaciones inmunitarias que impliquen la **expresión de proteínas HERVs facilitando la evolución hacia cuadros de autoinmunidad.**

Hace más de 20 años se comenzó a observar que en el suero de pacientes con cáncer y con VIH aparecían anticuerpos contra proteínas que parecían provenir de retrovirus endógenos. Ya con el avance de la tecnología se comprobó que, efectivamente, había retrovirus endógenos que se estaban transcribiendo. (Christopher Ormsby. Research Scientist - Centro de Investigaciones en Enfermedades Infecciosas, Instituto Nacional de Enfermedades Respiratorias "Ismael Cosío Villegas")

En una reciente CARTA dirigida a la EMA, asi como a la presidenta de la Comisión Europea y al presidente del Consejo de Europa, un grupo de reputados científicos y médicos, demuestra, basándose en evidencias científicas, que las vacunas génicas de ARN y ADN **pueden producir un síndrome COVID,** en lugar de prevenirlo, asi como ser la causa de efectos muy graves al facilitar la producción de microtrombosis en órganos como pulmones, corazón, riñón y cerebro.

https://doctors4covidethics.medium.com/urgent-open-letter-from-doctors-and-scientists-to-the-european-medicines-agency-regarding-covid-19-f6e17c311595

Por otra parte **J. Patrick Whelan MD PhD , en un documento publicado sobre comentarios previos a la aprobación de las vacunas covid por la FDA, el 9 de dic 2020:**

https://www.regulations.gov/document/FDA-2020-N-1898-0246

El pediatra y especialista en síndrome inflamatorio multisistémico (MIS-C). explica: "Me preocupa la posibilidad de que las nuevas vacunas destinadas a crear inmunidad contra la proteína pico del SARS-CoV-2 (incluidas las vacunas de ARNm de Moderna y Pfizer) tengan el potencial de **causar lesiones microvasculares en el cerebro, corazón, hígado y riñones** de una manera que actualmente no parece evaluarse en los ensayos de seguridad de estos posibles fármacos."

Ya que en base a estudios científicos publicados (reportados en el enlace arriba) parece probable que sólo la **spike protein sea la causante del síndrome covid** (no un virus completo) por lo que las vacunas génicas serían capaces de producirlo. En otras palabras, **las proteínas virales parecen causar daño tisular sin replicar activamente el virus.**

No podemos asegurar que el ARN encapsulado no se pueda comportar como un patógeno sintético, es decir como una virus like particle, que produzca efectos parecidos a la patología inflamatoria englobada en el síndrome Covid-19 ya que es un tipo de inmunopatología M2-TH2, y el virus artificial podría afectar principalmente a las células inmunes (macrófagos y linfocitos). Es de destacar que según notificación de Yellow Card (U.K.) la muerte por trastornos generales similares a los descritos como COVID-19, está asociada de manera muy notable con la vacuna covid **(20).**

Reputados científicos han destacado que la spike protein tiene una secuencia de aminoácidos similar al péptido Gp120 de la proteína de fusión del VIH (Luc Montaigner, Bill Gallaher, Roxana Bruno y Prashant Pradham) por lo que podría inducir linfopenia y, por tanto, inmunodepresión. (Universidad de Queensland, Australia y la Farmacéutica CLS) **(21)**

Por otra parte hay constancia de que las **vacunas de ARNm de Pfizer fueron comercializadas sin garantía suficiente de calidad en su fabricación,** lo cual genera importante incertidumbre añadida, a su eficacia y seguridad y demuestra que los organismos reguladores como la EMA y la FDA, son sometidos a "presiones diversas" para agilizar los trámites de aprobación sin las necesarias garantías. Adjuntamos enlace que explica, en base a una filtración de correos electrónicos, dichos aspectos.

https://www.bmj.com/content/372/bmj.n627?fbclid=IwAR3j4ys1ZDxsgk6R1xhs-GifCZXL8qWRGPjQzftNBbd7CiQbMwzjtJGIY3s

tampoco podemos descartar que este ARN truncado pueda expresar otras proteinas preocupantes, dada su homología con las sincitinas, y los riesgos que la expresión ectópica de las sincitinas suponen para la salud (esclerosis múltiple y esquizofrenia) **(22, 23, 24).** Asi como diabetes **(60).**

Según la EMA: (25)

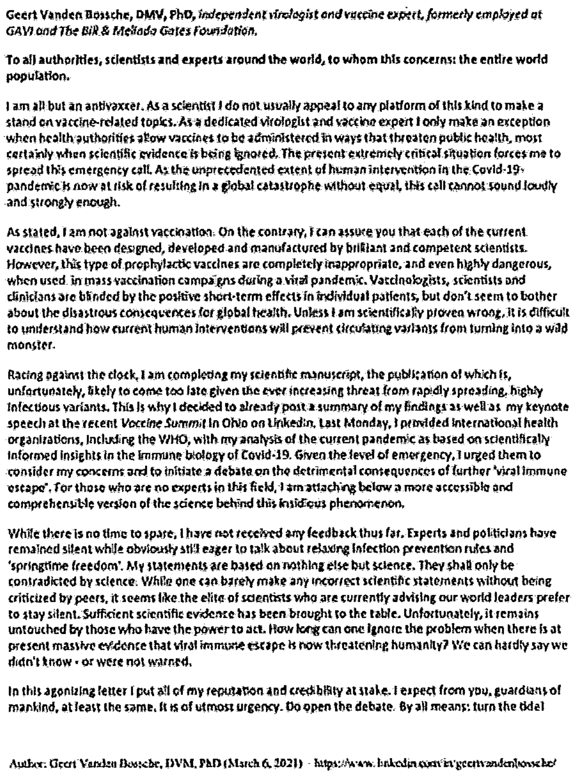
Los niveles de ARNm truncado "y las cantidades de una proteína potencial producida por el ARNm truncado serían demasiado bajas para constituir un riesgo de seguridad". Pero lo cierto es que nadie lo sabe con seguridad, pues igualmente reconoce: "La experiencia con la integridad del ARNm es limitada".

Otra preocupación derivada de las vacunas génicas es que la información transmitida por una sola proteina viral al sistema inmune de las personas, por las vacunas experimentales, esté en la base de seleccionar mutaciones que **provoquen cepas resistentes** a los posibles anticuerpos formados de manera demasiado selectiva, es decir, unicamente contra la Spike protein del virus, convirtiendo de esta manera, una epidemia fácilmente controlable por la inmunidad de grupo, (en la infección natural se produce inmunidad frente a diversos antígenos víricos) en una **epidemia monstruosa con continuos brotes, ocasionando "una catástrofe sin precedentes"** (sic)

Esta es la opinión del virólogo, experto en vacunas, Geert-vanden-Bossche, transmitida a la OMS mediante una carta abierta, en la que pide que se detenga la vacunación anticovid.

https://drive.google.com/file/d/1BMVudLApmWDt7MeVd_1l6LzCLXj3cND8/view
https://drive.google.com/file/d/1fB9ivJa5BRWmSh_ReJmgZhabR2ZzlYyZ/view

(transcripción de un fragmento de dicha carta)



Geert Vanden Bossche, DMV, PhD, ***independent virologist and vaccine expert, formerly employed at GAVI and The Bill & Melinda Gates Foundation.***

To all authorities, scientists and experts around the world, to whom this concerns: the entire world population.

I am all but an antivaxxer. As a scientist I do not usually appeal to any platform of this kind to make a stand on vaccine-related topics. As a dedicated virologist and vaccine expert I only make an exception when health authorities allow vaccines to be administered in ways that threaten public health, most certainly when scientific evidence is being ignored. The present extremely critical situation forces me to spread this emergency call. As the unprecedented extent of human intervention in the Covid-19 pandemic is now at risk of resulting in a global catastrophe without equal, this call cannot sound loudly and strongly enough.

As stated, I am not against vaccination. On the contrary, I can assure you that each of the current vaccines have been designed, developed and manufactured by brilliant and competent scientists. However, this type of prophylactic vaccines are completely inappropriate, and even highly dangerous, when used in mass vaccination campaigns during a viral pandemic. Vaccinologists, scientists and clinicians are blinded by the positive short-term effects in individual patients, but don't seem to bother about the disastrous consequences for global health. Unless I am scientifically proven wrong, it is difficult to understand how current human interventions will prevent circulating variants from turning into a wild monster.

Racing against the clock, I am completing my scientific manuscript, the publication of which is, unfortunately, likely to come too late given the ever increasing threat from rapidly spreading, highly infectious variants. This is why I decided to already post a summary of my findings as well as my keynote speech at the recent *Vaccine Summit* in Ohio on Linkedin. Last Monday, I provided international health organizations, including the WHO, with my analysis of the current pandemic as based on scientifically informed insights in the immune biology of Covid-19. Given the level of emergency, I urged them to consider my concerns and to initiate a debate on the detrimental consequences of further 'viral immune escape'. For those who are no experts in this field, I am attaching below a more accessible and comprehensible version of the science behind this insidious phenomenon.

While there is no time to spare, I have not received any feedback thus far. Experts and politicians have remained silent while obviously still eager to talk about relaxing infection prevention rules and 'springtime freedom'. My statements are based on nothing else but science. They shall only be contradicted by science. While one can barely make any incorrect scientific statements without being criticized by peers, it seems like the elite of scientists who are currently advising our world leaders prefer to stay silent. Sufficient scientific evidence has been brought to the table. Unfortunately, it remains untouched by those who have the power to act. How long can one ignore the problem when there is at present massive evidence that viral immune escape is now threatening humanity? We can hardly say we didn't know - or were not warned.

In this agonizing letter I put all of my reputation and credibility at stake. I expect from you, guardians of mankind, at least the same. It is of utmost urgency. Do open the debate. By all means: turn the tide!

Author: Geert Vanden Bossche, DVM, PhD (March 6, 2021) - https://www.linkedin.com/in/geertvandenbossche/

Esto se ha observado perfectamente en explotaciones animales en las que las vacunas han producido mutaciones que han ocasionado epidemias peores que la original.

5ª) Posible comportamiento de otras proteínas vacunales como análogos de proteínas HERVs del tipo de las sincitinas:

Debido a las homologías de secuencia encontradas entre las sincitinas y la Spike protein del SARS-CoV-2, es posible que la secuencia de ARN vacunal exprese péptidos antigénicos (epitopos inseguros) similares a las sincitinas o bien que determinados fragmentos derivados de la proteólisis metabólica de la Spike protein vacunal se acumulen en el organismo y tengan un comportamiento similar al que se observa en la expresión extemporánea de dichas proteínas sincitinas. Se sabe que la Sincitina 1 está anormalmente expresada en procesos autoinmunes como la esclerosis múltiple y la diabetes tipo 1, además de en cuadros pisiquiátricos como la esquizofrenia y el TOC. (22, 23,24,60).

También se podría producir este fenómeno por la activación de los propios HERV-W a consecuencia de la vacunación como se ha comprobado en determinadas agresiones tóxico-infecciosas y en el COVID grave (19,26).

6º) Problemas derivados de la interacción con el receptor ACE2: Se acepta que el receptor de la Spike protein del SARS-CoV-2 es el enzima ACE2 que se encuentra ampliamente distribuido por todo el organismo humano. Sin embargo, tiene una expresión predominante en los órganos sexuales masculinos: testículos, encontrándose tanto en las células de Leydig (productoras de testosterona) como en las de Sertoli (túbulos seminíferos) donde cumple importantes funciones de maduración testicular, no dependiente de hormonas, siendo imprescindible para la función reproductiva masculina (27). La posible unión de la proteína espiga vacunal con dicho receptor, o bien el depósito de complejos antígeno-anticuerpo en el mismo, puede dar lugar a la inflamación del órgano testicular con desarrollo de orquitis y posible infertilidad masculina.

También en otros órganos donde la expresión de ACE2 es elevada (28) como riñón, corazón e intestino, podrían producirse cuadros inflamatorios con insuficiencia funcional de los mismos. Ya se han observado muertes por problemas cardiacos e intestinales, según notificaciones de Yellow card (U.K.) y VAERS (USA).(62)

Por otra parte, en tejido nervioso, ACE2 es receptor de unas proteínas llamadas sinapsinas (29), muy importantes para diversas funciones de interconectividad neuronal, pudiendo su alteración ocasionar cuadros de diversa gravedad y complejidad.

La reducción de la funcionalidad ACE2 (30), ocasionada por la spike protein (infección o VACUNA) parece conducir a un aumento de la permeabilidad vascular. Si a esto añadimos lesión endotelial causada por los lípidos catiónicos de la LNP o por los detergentes vacunales, como el polisorbato 80, que lleva la vacuna de AstraZeneca (31), se va a producir un aumento de la expresión de "factor tisular" con activación de la vía extrínseca de la coagulación y con inhibición de la expresión de plasminógeno (disminución de la fibrinolisis). Esto favorecerá que se produzcan TROMBOSIS. Estas trombosis serán más frecuentes donde haya flujo sanguíneo lento (venas, capilares como los pulmonares y especialmente sinusoides). Esto concuerda con la relativa frecuencia de trombosis del seno cavernoso observadas, particularmente con la vacuna de AstraZeneca. (la trombosis del seno cavernoso puede afectar a la visión por la proximidad de nervios oculares).También se pueden producir trombosis en los miembros inferiores por la circulación sanguínea antigravedad.

7°) Silenciamiento génico: El ARN cumple en la célula diversas funciones de regulación, además de la traducción en proteínas de la información genética. Es bien conocido el fenómeno de silenciamiento génico producido por el ARN interferente (32) de manera que los ARN vacunales se pueden comportar como interferentes, bloqueando determinadas funciones vitales. Ha sido recientemente publicado que dicho ARN puede suprimir las proteínas supresoras de tumores, facilitando con ello la aparición de cánceres, especialmente derivados del sistema inmune (linfomas y leucemias linfocíticas):

MEDICAL SHOCKER: Scientists at Sloan Kettering discover mRNA inactivates tumor-suppressing proteins, meaning it can promote cancer.

Tuesday March 02, 2021 by: S.D. Wells

Tags: badhealth, covid cancer, Dangerous Medicine, dirty vaccines, DNA, DNA mrna, mRNA, mrna dangers, mRNA vaccines, RNA, vaccine wars, vaccines dirty

También es motivo de preocupación el silenciamiento génico de la proteína diana del receptor testicular ACE2, por lo que éste podría conducir a la **esterilidad masculina e incluso a la falta de desarrollo testicular en niños impúberes.**

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8°) Interacción con HERV-K: (33).

Otra homología encontrada (Gallaher) entre la Spike protein y proteínas Hervs humanas es con proteínas HERV-K (cromosoma 6), dichas proteínas tienen relación con enfermedades que afectan a las motoneuronas, por lo que una hiperexpresión de las mismas puede ocasionar enfermedades del tipo de las parálisis (**mielitis transversa, ELA**).

9°) Conformación priónica (34).

Investigaciones llevadas a cabo últimamente demuestran que el ARN de las vacunas covid puede inducir la formación de priones con potencial para causar enfermedades neurodegenerativas como Alzheimer y ELA.

Las proteínas de unión al ARN, TDP-43 y FUS y su plegamiento incorrecto y posterior depósito patológico podría explicar, tanto la pérdida de función sufrida en algunas enfermedades neurodegenerativas, como la ganancia de toxicidad observada en ELA (Esclerosis Lateral Amiotrófica).

Los resultados del estudio citado, indican que el ARN de la vacuna de Pfizer para Covid-19 tiene secuencias específicas que pueden inducir a TDP-43 y FUS a incorporarse al mismo en sus conformaciones patológicas como priones. En el análisis realizado se identificaron dieciséis repeticiones en tándem UG (ΨGΨG) y se identificaron secuencias ricas en UG (ΨG) adicionales. Se encontraron también secuencias de GGΨA. Posiblemente estén presentes secuencias de G cuádruplex, por lo que se necesita un programa informático para verificarlas. Además la proteína de pico (espiga) formada por la traducción de la vacuna de ARN se une a la enzima convertidora de angiotensina 2 (ACE2), una enzima que contiene zinc, y esta interacción tiene potencial para aumentar el zinc intracelular. Se ha demostrado que los iones de zinc causan la transformación de TDP-43 en su configuración patológica de prión.

Es sabido que el plegamiento de TDP-43 y FUS en sus conformaciones patológicas como priones causa ELA, degeneración lobar temporal anterior, enfermedad de Alzheimer y otras enfermedades neurológicas degenerativas. El hallazgo mencionado en el artículo citado, así como los riesgos potenciales adicionales, llevan al autor a creer que la aprobación regulatoria de las vacunas basadas en ARN para el SARS-CoV-2 fue prematura y la vacuna puede causar mucho más daño que beneficio.

10°) Posible inserción genómica del ARN vacunal en el ADN (35)(36).

Produciéndose mutagénesis inserciona1 en células en división celular, especialmente de la línea germinal (espermatocitos y ovocitos) e inmunitarias en regresión blástica por estímulo antigénico.

11°) Problemas derivados de las nanopartículas lipídicas LNP (37).

Los lípidos catiónicos ionizables son el excipiente crítico en los sistemas de LNP ya que impulsan el atrapamiento y la administración intracelular.

Pfizer contiene ALC-0315 que es el lípido catiónico, y el otro es **ALC-0159**, el péptido PEGilado.

SM-102 (heptadecan-9-yl 8 - ((2-hidroxietil) (6-oxo-6- (undeciloxi) hexil) amino) octanoato) es un lípido ionizable patentado que se utiliza para formar nanopartículas lipídicas en la **vacuna Moderna** COVID-19 .

La eliminación o aclaramiento de las nanopartículas lipídicas que encierran el ARN vacunal no está estudiado en humanos, pero los estudios realizado en ratas demostraron que pueden permanecer en los organismo durante meses y que **su toxicidad es muy elevada** (9).

La interacción de los lípidos catiónicos vacunales con moléculas vitales cargadas negativamente: aminoácidos, proteínas y A.N. produce diversas disfunciones, por ejemplo de enzimas, lo que puede conducir a diversas alteraciones bioquímicas y patología a largo plazo.

La interacción con los fosfolípidos de las membranas celular y mitocondrial produce **daño de los enzimas de la cadena respiratoria** que se encuentran en dicha membrana, ocasionando depresión de la respiración celular (**daño cardiovascular y hematológico**).

Daño hepático por toxicidad celular directa con hepatolisis periportal. Debido a que la eliminación de estos lípidos se produce exclusivamente por vía hepatobiliar.

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12°) Alergia y anafilaxia al polietilenglicol (38).

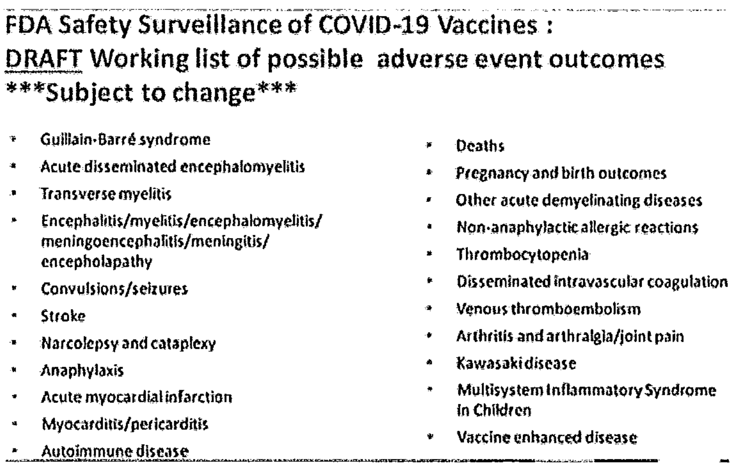
El polietilenglicol es uno de los lípidos que componen las nanocápsulas en que está envuelto el ARNm, es un lípido tóxico pero utilizado por sus ventajas, como excipiente en otros fármacos y diversos productos. Muchas personas se encuentran sensibilizadas al mismo por exposición previa, lo que supone que en el nuevo contacto con el polietilenglicol vacunal, y teniendo en cuenta que la vía de administración es parenteral y, por tanto muy directa, pueden desarrollar un cuadro anafiláctico que podría ser mortal.

13°) Síndrome de ADE: Antibody-dependent enhancement (enfermedad aumentada por vacuna).

Este es uno de los principales y más documentados problemas que presentan las vacunas COVID y no solamente las de ARNm sino todos los tipos, incluyendo las de virus inactivados, de antígenos protéicos y de ADN vectorizado.

En todas las pruebas con vacunas para SARS-CoV y virus similares (sincitial respiratorio), realizadas en todo tipo de animales (ratones, felinos y primates) se ha producido el fenómeno inmunológico conocido como mejora de la infección mediada por anticuerpos, o enfermedad aumentada por vacuna, que consiste en que, al ser expuesta la persona vacunada al virus salvaje o circulante, con posterioridad a la vacunación, en lugar de experimentar una protección, sufre una enfermedad más grave que la natural e incluso la muerte. **(39,40, 41, 42,43, 44).**

Todos estos posibles efectos adversos fueron publicados por la FDA.
(Center for Biologics evaluation and Research)



FDA Safety Surveillance of COVID-19 Vaccines :
DRAFT Working list of possible adverse event outcomes
Subject to change

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/meningoencephalitis/meningitis/encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

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II.- VACUNAS DE ADN VECTORIZADO (AstraZeneca, Janssen, SputniK, Cansino).

Los fármacos génicos que se están experimentando como vacunas COVID de este tipo, constan de un gen vírico, retrotranscrito a partir de la información contenida en la secuencia de ARN vírica correspondiente a la Spike protein. Este ADN, para poder entrar en las células, está vehiculizado en un vector viral, es decir, un adenovirus modificado genéticamente para que no se pueda reproducir. Hay varios tipos de vectores según el tipo de vacuna, generalmente son adenovirus humanos (ad. tipo 5, Ad. tipo 26, vacunas Sputnik y Janssen, respectivamente) pero también los hay de chimpancé como es el caso de la vacuna de AstraZeneca (ChAdOx1 n CoV-19):

La vacuna **ChAdOx1 nCoV-19 (AZD1222)** consiste en el vector de adenovirus de simio de **replicación deficiente** ChAdOx1, que contiene la glicoproteína de superficie estructural de longitud completa (proteína de pico) de SARS-CoV-2, con una secuencia líder del activador del **plasminógeno** tisular. ChAdOx1 nCoV-19 expresa una secuencia codificante de codón optimizado para la proteína de pico (número de acceso de GenBank MN908947).

Sin embargo, es conocido que un mismo ARNm puede codificar para diferentes proteínas en función de situación y tipo celular **(45)**, por lo que se podrá sintetizar la spike protein pero no podemos descartar que se produzcan **también otras proteínas, con funciones desconocidas o interferentes.**

En cuanto a su funcionamiento, se supone que el ADN transcribirá un ARNm que codificará la Spike protein del SARS-CoV-2 y a partir de este momento el proceso sería similar al que ocurre en las vacunas de ARN m.

Posibles riesgos o efectos adversos:

1°.- El vector ChadOx1, a diferencia de otros vectores similares (Chad2), se caracteriza por su **alta infecciosidad** pudiendo infectar a todas las células del organismo menos a los eritrocitos, a la vez que su estímulo del sistema inmune es menor **(46)**. Por esta razón, y por contener restos de ADN humano debido a la utilización de líneas celulares humanas: **Células T-REx-293, derivadas de la línea celular HEK-293** (células embrionarias de riñón humano procedente de aborto), para cultivo, no es posible descartar el riesgo de mutagénesis insercional **(47)**, particularmente en células inmaduras en proceso de división celular como las células germinales o inmunes.

2°.- Inmunodeficiencia inducida por las vacunas de vector viral:

Otro problema relacionado con los vectores de adenovirus es su posibilidad de inducir inmunodeficiencia. Esto se ha comprobado con el vector Ad. tipo 5 cuando se han probado en humanos vacunas con dicho vector viral, puesto que , particularmente los varones vacunados, eran más susceptibles de ser infectados con el VIH **(48).** Tampoco es posible descartarlo completamente en los vectores de adenovirus de simio como la vacuna de Oxford y AZ ya que la modificación de la línea celular HEK-293 se hace con adenovirus de tipo 5.

Por otra parte es sabido que la **Universidad de Queensland,** Australia, abandonó un proyecto de vacuna COVID vectorizada debido a que en los ensayos clínicos se estaban produciendo positivos en pruebas de VIH **(49).**

3°.- Problemas en la coagulación: (informe de evaluación de la EMA) (50).

La vacuna de AstraZeneca tiene una secuencia de proteína activadora del **plasminógeno** etiquetada en la secuencia codificante de la Spike protein. El activador del plasminógeno es importante en la coagulación sanguínea, si se producen anticuerpos contra éste, o se produce su silenciamiento génico, se ocasionarán problemas en la coagulación, **trombosis** principalmente, pero también se podrían producir hemorragias, lo que ocasionaría un **accidente cerebrovascular o ataque cardiaco.** Esto se está observando actualmente como efecto adverso de dicha vacuna, por lo que varios países han decidido interrumpir su inoculación. (concretamente, 17 países europeos han suspendido la vacunación con AstraZeneca, a 16/3/2021) **(51)**

Se ha observado con esta vacuna, de manera recurrente, la **trombosis del seno cavernoso.** La reducción de la funcionalidad ACE2, ocasionada por la spike protein **(52)** (infección o VACUNA) parece conducir a un aumento de la permeabilidad vascular, si a esto añadimos lesión endotelial causada por detergentes vacunales: polisorbato 80 que también lleva la vacuna AstraZeneca **(31),** se va a producir un aumento de la expresión de "factor tisular" con activación de la vía extrínseca de la coagulación y con inhibición de la expresión de plasminógeno (disminución de la fibrinolisis). Hay que recordar que **la vacuna AstraZeneca contiene un gen de plasminógeno,** lo que puede agravar aún más la probabilidad del daño trombótico que puede producir la Spike protein vacunal.

En cuanto al SENO CAVERNOSO, es una zona sinusoidal venosa que, por su localización anatómica, está cerca de las ADENOIDES (amígdala faríngea) y el tejido linfoide (células inmunes) es una de las dianas genéticas de la spike protein. Por el seno cavernoso circula la arteria carótida interna y el 6° par craneal (nervio motor ocular lateral) y por su pared

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externa otros nervios oculares (3°, 4° pares) estando también próximo el nervio oftálmico. Esto explicaría los **frecuentes problemas oculares, incluida la ceguera**, en los vacunados.

Sin embargo, no se puede descartar que **todas las vacunas para COVID produzcan problemas en la coagulación,** pues la regulación a la baja de ACE2, debido a su interacción con la Spike protein expresada por dichas vacunas, puede contribuir al aumento del riesgo trombótico por su causa **(52).**

4°.- Trombocitopenia (53,54).

Se ha comprobado que el vector recombinante derivado de Adenovirus 5 se une rápidamente a las plaquetas sanguíneas circulantes, provocando trombocitopenia. Ad5 activó tanto las plaquetas como las células endoteliales directamente in vitro, como lo demuestra la inducción de P-selectina y la formación de cadenas de plaquetas con factor von Willebrand, y también in vivo, como lo demuestra la inducción de ARN mensajero de E-selectina. La activación plaquetaria derivada de esta unión en los sinusoides, particularmente hepáticos, genera microtrombos pero no se descarta que sea también un mecanismo que explique las trombosis sinusoidales que se producen tras la vacunación. En general todas las vacunas COVID que utilizan vectores de adenovirus, utilizan el Adenovirus tipo 5 en un momento u otro de su elaboración. Por ej la AstraZeneca, lo emplea para la producción de la línea celular HEK-293. **(50).**

"Las trombosis venosas eran un poco raras, no se correspondían con las que se suelen ver en la población general. Eran inusuales por ser especialmente graves. Normalmente son algo serio, pero en algunos casos eran trombosis masivas que afectaban no solo al cerebro, sino a otros órganos, como el bazo, el hígado, los pulmones, el sistema venoso profundo... Y se ha observado también que en algunos pacientes además de la trombosis tenían las plaquetas muy bajas. Eso es muy extraño entre personas que tienen una trombosis venosa normal y corriente. Lo que se está estudiando ahora es que pueda ser un fenómeno o bien parecido a la coagulación intravascular diseminada o un fenómeno disinmune y que eso sea lo que está provocando que la sangre se trombose en el sistema venoso y que haya una afectación del número de plaquetas tan llamativa" en palabras de David García Azorín, vocal de la Sociedad Española de Neurología (El País, 18 marzo 2021) **(55).**

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5º.- Utilización de células embrionarias humanas procedente de aborto: (50: pág. 14)(56).

Para la fabricación de la vacuna AZD1222 se ha utilizado una línea celular recombinante: T-REx-293 cell elaborada a partir de células HEK293 cell line que proceden de riñón de embrión humano abortado. Además de las posibles consideraciones éticas, en estas células quedan siempre residuos de ADN que resulta tóxico y puede producir cáncer **(47)**. Además en el desarrollo de las células de cultivo T-REx, se emplea el adenovirus humano de tipo 5 asociado con el riesgo de producir inmunodeficiencia **(48).**

6º.- Otros excipientes: Polisorbato 80.

El polisorbato 80 se emplea como emulsionante para mezclar los componentes vacunales, pero además de su conocida toxicidad, los polisorbatos administrados por vía parenteral se han asociado con graves efectos adversos incluyendo la muerte de neonatos **(58)**, puede contribuir al daño endotelial facilitando la producción de trombos **(31).**

Tampoco se ha utilizado en los ensayos clínicos de la vacuna AstraZeneca un **placebo inerte** sino la vacuna meningocócica tetravalente: Nimenrix de Pfizer. Por lo que se hace más difícil valorar los efectos adversos de dicha vacuna génica en los ensayos clínicos.

III.- VACUNAS DE SUBUNIDADES PROTEICAS (Novavax y Sanofi/GSK) en desarrollo: fase 3 y fase 2 respectivamente.

IV.- VACUNAS DE VIRUS INACTIVADOS (vacunas chinas: Sinovac, Sinopharm).

Su difusión es menor, sabemos que se están utilizando en países de América Latina como Perú, mientras que en Europa no se están distribuyendo.

Suponemos que se utilizan, para su producción, cultivos de células VERO E6, (células de riñón de mono) puesto que en otras células como las humanas no se ha demostrado el crecimiento del SARS-CoV-2. **(61)**

El principal problema de ambos tipos de vacunas (subunidad proteica y virus inactivados) es la producción de **Síndrome de ADE o enfermedad aumentada por vacuna**, tras la exposición ulterior al virus circulante u otros coronavirus.

Este efecto adverso es común a todo tipo de vacunas COVID debido a las características de los coronavirus y al tipo de reactividad inmune que producen, habiéndose comprobado exhaustivamente **(39, 40, 41, 42, 43, 44)**. Es particularmente preocupante, según algunas diferencias raciales, de manera que la raza negra y la hispanoamericana son más susceptibles a desarrollarlo. Nos llama particularmente la atención que, por ejemplo, los estudios clínicos en fase 3 de la vacuna de ARNm de Pfizer, hayan experimentado con tan pocos individuos de ambas razas (59).

Es de destacar también el hecho de que no se ha realizado **desafío viral**, es decir, exposición de los vacunados al virus salvaje por lo que no se puede descartar la **principal preocupación** que suscitan estas vacunas: La **enfermedad aumentada por vacuna o síndrome de ADE**, ya que en los estudios de desafío con animales todos sufrieron enfermedad grave o murieron (Fuente Robert F. Kennedy Jr. presidente de Children´s health defense. 22 mayo 2020) y se va a exponer a millones de seres humanos a esta eventualidad.

Tampoco hubo prevención de la infección en los animales vacunados, por lo menos con alguna de estas vacunas. Todos los monos vacunados tratados con la vacuna Oxford se infectaron cuando se los desafió, según se juzga por la recuperación del ARN genómico del virus de las secreciones nasales. No hubo diferencia en la cantidad de ARN viral detectado en este sitio en los monos vacunados en comparación con los animales no vacunados. Es decir, todos los animales vacunados estaban infectados. (fuente: ¿Funcionó la vacuna Oxford Covid en monos? Realmente, no, por William A. Haseltine). Por lo que no se sabe si la vacunación evitará la trasmisión del virus, pudiendo contribuir de esta manera, **A LA DIFUSIÓN DE VARIANTES MAS PELIGROSAS** para los que no se habrán desarrollado anticuerpos (Carta del Dr. Geert-vanden-Bossche a la OMS).

También hay que destacar que, las vacunas génicas, han hecho los **estudios de fase tres con personas jóvenes y sanas mayoritariamente,** muy pocos mayores de 70 años, habiéndose descartado voluntarios que presentaban ya anticuerpos contra el SARS-CoV-2 (por posible ADE), personas con patologías activas y polimedicados, así como embarazadas y niños. Por lo que nos parece **una grave irresponsabilidad,** estar utilizándolas en dicha población.**(62)**

Es importante insistir en el grave riesgo de desarrollo de **enfermedades autoinmunes (60, 22)**, que no se diagnosticarán, probablemente, hasta pasado un tiempo variable tras la inoculación.

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Finalmente, desde el punto de vista ético, también hay que considerar que todas las vacunas génicas para covid han utilizado, en una u otra forma, células procedentes de aborto fetal humano (56,57).

CONCLUSIONES.

A) **Todos los tipos de vacunas covid pueden producir ADE:** enfermedad aumentada por vacuna (Vaccine enhanced disease).

B) Se han probado con muy pocos individuos de las razas más expuestas a dicho síndrome, como son LA RAZA NEGRA Y LA HISPANOAMERICANA.

RESPECTO A LAS denominadas vacunas génicas **(RNAm y DNA vectorizado)**

C) **NUNCA** antes se han experimentado en la población humana de manera generalizada.

D) Están en **FASE EXPERIMENTAL** (fase IV post-comercialización).

E) Tienen una **APROBACIÓN CONDICIONADA** para uso de emergencia.

F) En las fases de prueba se ha **descartado a los voluntarios con anticuerpos covid** (debido al posible desarrollo de ADE) (Pfizer).

G) Las fases de prueba se han hecho principalmente con individuos jóvenes y sanos, mientras que el nº de personas mayores de 65-70 años y con patologías o polimedicadas ha sido **INSUFICIENTE.**

H) En las conclusiones de los estudios de esta vacunas no se descarta que **se pueda evitar la transmisión** y, por tanto el contagio a individuos sanos.

I) Tampoco se sabe si protegerán de **nuevas variantes víricas ni cuánto durará la protección.**

J) **No hay evidencia de que no puedan producir trombosis y trombocitopenia,** debido al elevado nº de casos que se han producido tras la inoculación de las mismas y en un **periodo de tiempo muy corto.**

K) **Hay CIENCIA BÁSICA** que obliga a **DESCARTAR EL POSIBLE RIESGO** de los siguientes **efectos adversos graves que no se han tenido en cuenta,** algunos de los cuales se pueden producir a medio o largo plazo:

1.- **PATOLOGÍA NEUROLÓGICA Y PARÁLISIS.**

2.- **ENFERMEDADES AUTOINMUNES COMO ESCLEROSIS MÚLTIPLE Y DIABETES.**

3.- **ESTERILIDAD FEMENINA Y ABORTOS.**

4.- **ESTERILIDAD MASCULINA.**

5.- **INMUNODEFICIENCIA.**

6.- CÁNCER, especialmente LEUCEMIAS Y LINFOMAS.

7.- ESQUIZOFRENIA Y TRASTORNOS DEL COMPORTAMIENTO (TOC).

8.- DEMENCIA Y ELA.

9.- ALTERACIONES GENÉTICAS POR SILENCIAMIENTO GÉNICO Y/O MUTAGÉNESIS INSERCIONAL.

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FIRMAS.

Este documento está avalado por los siguientes médicos y biólogos.

1. Mª José Martínez Albarracín. Universidad de Murcia. (actualmente no colegiada)
2. Manuel Alejandro Sousa Escandón Doctor por Universidad de Santiago de Compostela. Colegiado 2702700 (Lugo)
3. Luis Marcelo Martínez. Médico genetista. Universidad de Buenos Aires MN 107982
4. Ricardo Falcón Lambán. Doctor por la Universidad de Zaragoza. Número de colegiado 50.0549
5. Emilio Morales Prado. Doctor por Universidad de Sevilla. Colegiado: 5466 del RICOM de Sevilla.

1. Jon Ander Etxebarria Garate - Licenciado en Biología por la Universidad de Oviedo. Facultad de León Colegiado Nº Col. 2 – Colegio de Biólogos de Euskadi
2. Almudena Zaragoza Velilla - Licenciada en Biología por la Universidad Autónoma de Madrid Nº Col. 19086M – Colegio de Biólogos de Madrid
3. Ane Miren Yusta Sanz - Licenciada en Biología de Ecosistemas por la Universidad del País Vasco Nº Col. 1584- Colegio de Biólogos de Euskadi

6. Carlos González de la Cuesta Lic. Universidad de Santiago Doctorado en Univ. de Navarra N° Colegiado 2235, Ourense
7. Ana María Montenegro Portillo. Doctora por la Univ de Granada. N° Colegiada 08324
8. Silvano Baztán Guindo, Doctor en Med. Univ.de Navarra, N° colegiado 313103445
9. José Manuel Esteban Hernández. Doctor por Universidad Literaria de Valencia
10. Juan José Martínez Licenciado la Universidad de Valladoloid. Doctor por la Universidad del País Vasco N° Colegiado 202003256, Guipúzcoa.
11. Manuel Gutiérrez Ontiveros Universidad de Sevilla N° de Colegiado 8803
12. Rafael Reinoso Casado. Universidad de Navarra Colegiado 26/1651
13. Carmen Soler Arnedo Universidad de Valencia Colegiada 14762
14. Consuelo Vazquez Picos Facultad Oviedo. N° colegiada 33063647.
15. Buenaventura Hernández Machín. Univ. de Las Palmas de Gran Canaria. N° colegiado: 35/35/05158
16. Blanca Asunción Lario Elboj Universidad de Zaragoza N° de colegiado 50/11417

4. Pablo Honduvilla Ruiz – Licenciado en Biología por la Universidad de Valencia N° Col. 30401-CV – Colegio Oficial de Valencia.
5. Carmen Zaballa Ramos - Licenciada en Ciencias Biológicas por la Universidad del País Vasco.
6. Dr. Francisco Molino Olmedo - Doctor en Ciencias Biológicas por la Universidad de Granada.
7. Jesús García Felgueroso - Licenciado en Biología por la Universidad de Oviedo.
8. José Manuel Cantó Sánchez - Licenciado en Biología por la Universidad de Granada. Catedrático de Biología y Geología.
9. Marina Castells Quero – Licenciada en Biología por la Universitat de Barcelona.
10. José Muñoz Moreno – Licenciado en Biología Fundamental por la Universidad de Granada.
11. Bartomeu Payeras Cifre – Licenciado en Biología por la Universidad de Barcelona.
12. Andrea Nuevo Álvarez - Licenciada en Biología por la Universidad de Oviedo.
13. Estíbaliz Tello Mendiguchia - Licenciada en Biología por la Universidad de Barcelona.
14. Sergio Acosta López – Licenciado

17. Esther Vilarnau Reig. Universidad Autonoma de Barcelona, N° Col. 28034 Barcelona.
18. Eva Monge Casares. Universidad de Valladolid.
19. Concepción Ortiz de Zárate Maguregui. Universidad del País Vasco UPV (EHU) N° Col. 33_09732 Asturias.
20. María Carmen Martínez Poyato Universidad de Murcia N° Colegiada en Murcia 302921
21. Emilio Guzman Sánchez N° colegiado 8812, Zaragoza
22. Ana Mar Gil Urnicia. Universidad de Navarra. N° Colegiado 4.765 Navarra
23. Juana María Legaz Domench Universidad de Navarra. CNP:98-0007636-49
24. Dictino García Gonzalo Universidad de Bilbao N° Colegiado 5005957, Vitoria
25. Teresa Arraez Salvago Universidad de Granada. N° Colegiada 1805727 Granada
26. José María Olivares Barrero. Universidad de Granada. N° Colegiado 18/1805431.
27. José Maria Altarriba U. Autónoma Barcelona N° Colegiado 3457 Oviedo
28. Pedro López Bastida Universidad de Murcia. Número de colegiado 2546
29. María Amparo Soriano Gil Univ. Literaria de Valencia, N° Colegiado 464617462
30. Francisco Javier Ramos Alija. N°

en Biología por la Universidad de Alicante.

15. Nayely Espinoza Covarrubias - Licenciada en Biología por la Universidad Autónoma Metropolitana de México.
16. Rebeca Lavandera García – Licenciada en Biología por la Universidad de Oviedo.
17. Daniel de la Torre Llorente - Doctor en Ciencias Biológicas por la Universidad Autónoma de Madrid. Profesor titular de universidad.
18. Rosa Domingo Bernardo – Licenciada en Biología por Universidad Complutense de Madrid.
19. Alejandro Polo Santabárbara - Licenciado en Biología Ambiental por la Universidad Autónoma de Madrid.
20. María Jesús Blázquez García - Licenciada en Biología por la Universidad Complutense de Madrid. Catedrática de Biología y Geología.
21. Miguel Cancela Bañuelos – Licenciado en Biología por la Universidad Autónoma de Madrid.
22. María Dolores Munuera Martínez - Licenciada en Biología por la Universidad de Murcia.
23. Laura Tobaruela Lana – Licenciada

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Colegiado 242403479, León.

31. Mª Jesús Galán Dueñas Nº Colegiado 4109943.
32. Maria Fuentes Caballero Universidad Central Barcelona Nº Colegiado 6974. Cadiz.
33. Koldo Aso Medialdea Universidad de Valladolid. Nº Colegiado 3399, Donostia
34. Jose Luis Jiménez Sales. Universidad de Salamanca. Nº Colegiado 10/1002170, Cáceres.
35. Carlos Muñoz-Caravaca Ortega Universidad de Valencia Nº Colegiado 024617772
36. Luis Fernando Cámara. Universidad del País Vasco. Nº Colegiado 48-3200
37. Tatiana Botella Arias Universidad de Barcelona. Nº Colegiado 32.461
38. José Ramón Blanco Sánchez Universidad de Alcalá de Henares Nº Colegiado 2867889
39. Angeles Gimeno Lopez Universidad Autonoma Bcn Nºcolegiado 18768
40. Ricardo Arriola López. Universidad País Vasco. Nº Colegiado 3855, Gipuzkoa
41. Blanca Rodríguez Tuñas. Facultad de Medicina de Sevilla. Actualmente no colegiada
42. Angustias Ferrer Pertiñez.

en Biología por la Universidad de Barcelona.

24. Fernando López-Mirones – Licenciado en Biología por la Universidad Complutense de Madrid.
25. María Esperanza Manzano Piedras - Licenciada en Biología por la Universidad Autónoma de Madrid.
26. Jon Ortega Rodrigáñez - Licenciado en Biología por la Universidad Autónoma de Madrid.
27. Jacinto Martínez Ródenas – Licenciado en Biología por la Universidad de Murcia.
28. Isabel López López – Licenciada en Biología por la Universidad de Barcelona.
29. Xabier Jauregui García – Licenciado en Biología por la Universidad del País Vasco.
30. Felisa Basaldua Lázaro – Doctora en Biología por la Universidad del País Vasco.
31. Eduardo Gabriel Lucía Manica – Licenciado en Biología por la Universidad Veracruzana
32. Gabriel Cantó Martínez – Licenciado en Ciencias Ambientales por la Universidad de Murcia. Profesor de Biología y Geología.
33. Alejandro Iruela Alonso – Licenciado en Ciencias Ambientales

N° Colegiado. 11.058

43. Francisco Tomás Verdú Vicente. Universidad de Valencia. N° Colegiado 14.268 Valencia.
44. María Jesús Martinez Yuste. Universidad de Zaragogoza N° Colegiada 5007480
45. Mª Luisa Escandón Pérez. Universidad de Sevilla N° Colegiada 33/4112465
46. José Maria Méndez Bayón. Universidad de Valladolid, N° Colegiado 26/9-4421, en La Rioja.
47. Sofía María Jesús Labrada Trenado. Universidad Central Barcelona. N° Colegiada 23916, Barcelona.
48. Susanna Petit Petermann. Universidad Autónoma de Barcelona. Ejerzo en Suiza n° col Suiza 035967.
49. Pedro Luis Rocamora Jover. N° Colegiado 6287, Alicante.
50. Carmen Martí Amiguet. Universidad de Valencia. N° Colegiado 2971 en Gipuzkoa.
51. Dinah Morales Perez. Universidad de Sevilla N° Colegiado 213978-3 (Huelva).
52. Juan Antonio Martínez Candel. Universidad de Valencia N° colegiado 464609360
53. Raquel Fuentes Cuenca. Universidad de Alicante. ES 03-8248-7.
54. Concha Antón Antón. Universidad de Valencia. N° Colegiado 10.812
55. María Europa Sierra Benítez. Facultad

por la Universidad Rey Juan Carlos de Madrid.

34. Francisco Javier Rueda – Licenciado en Biología por la Universidad Complutense de Madrid
35. Ramiro Castillo Burgos – Licenciado en Biología por la Universidad Nacional de Trujillo.
36. Vicente I. Costa Ciscar – Licenciado en Biología por la Universidad de Valencia.

Medicina de Cádiz. Actualmente no colegiada.

56. Angustias Ferrer Pertiñez. Nº Colegiada 11.058, Sevilla
57. Concha Antón. Universidad de Valencia Nº Colegiada 46-10812 .
58. M Susana Sanz Cardeñosa. Universidad autónoma Barcelona. Nº Colegiada 36104.
59. Servando López Gómez. Médico rehabilitador. Nº Colegiado 111104692, Cádiz.
60. Elena Castro Méndez. Universidad de Sevilla. Nº Colegiada 41/13027.

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Doctors say CDC should warn people the side effects from Covid vaccine shots won't be 'a walk in the park'

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Berkeley Lovelace Jr.@BERKELEYJR

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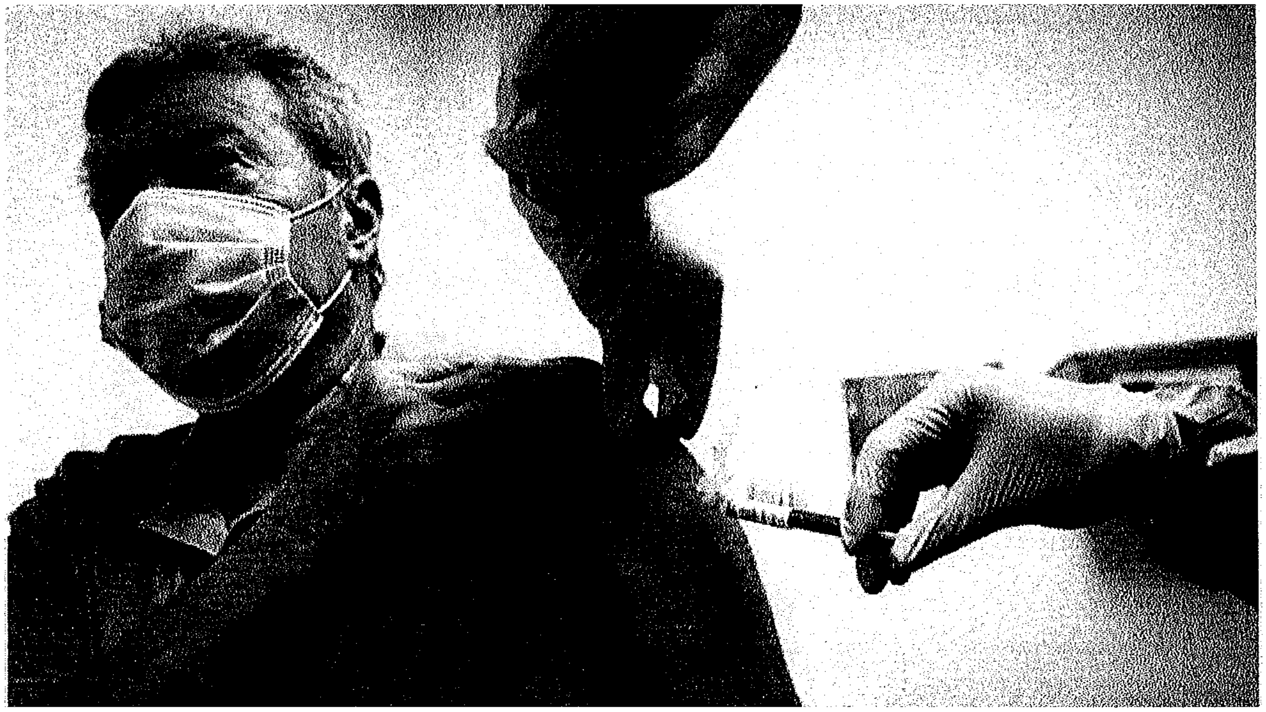
KEY POINTS

- The CDC must be transparent about the side effects people may experience after getting their first shot of a coronavirus vaccine, doctors urged during a meeting Monday with CDC advisors.
- Dr. Sandra Fryhofer said that both Pfizer's and Moderna's Covid-19 vaccines require two doses and she worries whether her patients will come back for a second dose because of potentially unpleasant side effects after the first shot.
- Both companies acknowledged that their vaccines could induce side effects that are similar to symptoms associated with mild Covid-19, such as muscle pain, chills and headache.

In this article

- MRNA-1.42 (-1.07%)



A volunteer is injected with a vaccine as he participates in a coronavirus disease (COVID-19) vaccination study at the Research Centers of America, in Hollywood, Florida, September 24, 2020.

Marco Bello | Reuters

Public health officials and drugmakers need to warn people that coronavirus vaccine shots may have some rough side effects so they know what to expect and aren't scared away from getting the second dose, doctors urged during a meeting Monday with CDC advisors.

The recommendations come as states prepare to distribute the potentially life-saving vaccinations as early as next month.

Dr. Sandra Fryhofer of the American Medical Association said both Pfizer's and Moderna's Covid-19 vaccines require two doses at varying intervals. As a practicing physician, she said she worries whether her patients will come back for a second dose because of the potentially unpleasant side effects they may experience after the first shot.

WATCH NOW

VIDEO

Here's a look at the ultra-cold freezers needed to store Covid vaccines

"We really need to make patients aware that this is not going to be a walk in the park," Fryhofer said during a virtual meeting with the Advisory Committee on Immunization Practices, or ACIP, an outside group of medical experts that advise the CDC. She is also a liaison to the committee. "They are going to know they had a vaccine. They are probably not going to feel wonderful. But they've got to come back for that second dose."

Participants in Moderna and Pfizer's coronavirus vaccine trials told CNBC in September that they were experiencing high fever, body aches, bad headaches, daylong exhaustion and other symptoms after receiving the shots. While the symptoms were uncomfortable, and at times intense, the participants said they often went away after a day, sometimes sooner, and that it was better than getting Covid-19.

Both companies acknowledged that their vaccines could induce side effects that are similar to symptoms associated with mild Covid-19, such as muscle pain, chills and headache.

One North Carolina woman in the Moderna study who is in her 50s said she didn't experience a fever but suffered a bad migraine that left her drained for a day and unable to focus. She said she woke up the next day feeling better after taking Excedrin but added that Moderna may need to tell people to take a day off after a second dose.

"If this proves to work, people are going to have to toughen up," she said. "The first dose is no big deal. And then the second dose will definitely put you down for the day for sure. ... You will need to take a day off after the second dose."

During the meeting on Monday, Dr. Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, said the agency would work to develop guidance if a health-care worker got a vaccine and then felt unwell the next day.

"How does that impact planning on a hospital level in terms of which staff gets vaccinated which day?" she said.

WATCH NOW

VIDEO

What we do and don't know about the highly effective Covid-19 vaccines

Patsy Stinchfield, a Children's Minnesota nurse practitioner, said officials and drugmakers could try talking about the side effects in a more positive way. She said they could use language such as "response" instead of "adverse reaction."

"These are immune responses," said Stinchfield, a past voting member of the committee. "And so if you feel something after vaccination, you should expect to feel that. When you do, it's normal to have some arm soreness or fatigue, some body aches and maybe even a fever. It sounds like in some of these trials, maybe even having to stay home from work."

Dr. Grace Lee, a professor of pediatrics at the Stanford University School of Medicine, agreed, saying a coronavirus infection could be detrimental to an entire family.

"If they have to miss 14 days of work, that's a huge amount to miss," said Lee, who is a member of the ACIP, told the CDC. "I think we do have to think about that the vaccine itself. While there may be some short term work loss issues, I do think that has to be balanced with the risk of getting an infection."

Stinchfield said some people in the trials have actually been disappointed when they don't suffer the side effects being reported by others, thinking they must have gotten the placebo.

The committee meeting comes three days after Pfizer and its partner BioNTech applied for an emergency use authorization from the Food and Drug Administration for their coronavirus vaccine.

The FDA process is expected to take a few weeks, and an advisory committee meeting to review the vaccine has been scheduled for early December. Some Americans could get their first dose of the vaccine in about a month.

ACIP is expected to call an emergency meeting to make specific recommendations on distribution once the FDA authorizes a vaccine.

Federal agencies are already sending vaccination plans around to staff. Five agencies have started telling employees they could receive Pfizer's or Moderna's Covid-19 vaccine in as little as eight weeks, a person with firsthand knowledge of those plans told CNBC on Friday.

https://www.cnbc.com/2020/11/23/covid-vaccine-cdc-should-warn-people-the-side-effects-from-shots-wont-be-walk-in-the-park-.html?__source=iosappshare%7Ccom.apple.UIKit.activity.Mail

Emergency Use Authorization Toolkit

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ASTHO LEGAL PREPAREDNESS SERIES
EMERGENCY USE AUTHORIZATION TOOLKIT

Section 564 of the Federal Food, Drug, and Cosmetic Act

Fact Sheet

Overview

An Emergency Use Authorization (EUA) under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)1 allows for the special use of drugs and other medical products during certain types of emergencies.2 The EUA authority was added by the Project BioShield Act of 2004, which amended the FD&C Act, among other things.3

As of March 2012, Congress is in the process of reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA). The U.S. House and Senate have adopted their own versions of reauthorizing legislation, both of which provide greater flexibility for HHS and FDA to approve the use of medical products in emergencies but differ in some specific provisions. Congress is likely to convene a conference committee to reconcile the differences between the bills. The legislation ultimately passed may affect Section 564 and other provisions of the FD&C Act as described below. Please see ASTHO EUA Current Issues Winter 2012 for more information about reauthorization and its potential impact on EUAs and related issues. (Download a printable PDF.)

What the Law Does

An EUA permits the use of unapproved medical products (drugs, biologics [e.g., vaccines], and devices [e.g., diagnostics]) or the use of approved medical products in unapproved ways to diagnose, treat, or prevent serious diseases or conditions caused by chemical, biological, radiological, or nuclear (CBRN) agents if certain criteria contained in FD&C Act §564 are met.3 Under the FD&C Act, drugs, biologics (e.g., vaccines), and devices are required to meet certain requirements for safety and efficacy before they are approved by the Food and Drug Administration (FDA) to treat particular diseases or conditions in specified ways.

Traditionally, there are three phases for the development of drugs under the FD&C Act: pre-investigational new drug (pre-IND); investigational new drug (IND); and a new drug application (NDA).4 Each of these stages has statutory and regulatory requirements that must be satisfied. An EUA is not part of this traditional development pathway; it is a separate process used only during emergencies and is not part of the regular drug approval process.4 It is not required that a drug proposed for an EUA be at a specific point on the drug development pathway.4

The FDA has criteria it must follow under the FD&C Act when it decides whether to issue an EUA. The FDA places conditions on the authorization that must be followed when using a product under an EUA. If a product has been approved by the FDA and is being used according to the FDA label requirements, the product does not require that an EUA be issued.5

Liability Protections
An EUA authorization under FD&C Act §564 does not contain or confer any tort liability protections by itself.6 However, medical products authorized under an EUA qualify as countermeasures (e.g., vaccines, drugs, devices) covered under the Public Readiness and Emergency Preparedness (PREP) Act, which provides immunity from tort liability, if the medical products are specified in the PREP Act declaration.7 Medical products used pursuant to an EUA must be used and administered according to the terms of the EUA and included in the PREP Act declaration for PREP Act coverage to arise.

(See ASTHO PREP Act Fact Sheet.) Other federal statutes and programs including but not limited to the Federal Tort Claims Act8 and the National Vaccine Injury Compensation Program9 may also provide liability protections depending on the particular circumstances of an event.6

How the Law Works

FD&C Act §564 establishes requirements for issuing an EUA: (1) the determination that an emergency exists; (2) the declaration of an emergency; and (3) a finding by the FDA that specified criteria have been met.

Determination that an Emergency Exists
The FD&C Act requires that one of the following three cabinet secretaries makes a determination that an emergency exists before an EUA is authorized:

- If the secretary of the Department of Homeland Security determines that there currently exists, or is significant potential for, a domestic emergency involving a heightened risk of attack using specified CBRN agents.1
- If the secretary of the Department of Defense (DoD) determines that there currently exists, or is significant potential for, a military emergency involving a heightened risk to U.S. military forces of attack using specified CBRN agents.1
- If the secretary of the Department of Health and Human Services (HHS) determines that there is a public health emergency under the Public Health Service Act (PHS Act) §31910 that affects, or has significant potential to affect, national security and involves specified CBRN agents and diseases or conditions attributable to such agents.1

Declaration of an Emergency
If an emergency has been determined to exist, the HHS secretary can declare an emergency justifying the authorization of an EUA under FD&C Act §564.1,6 The §564 declaration of emergency is different from a determination of public health emergency under PHS Act §319 and a declaration of a public health emergency under the PREP Act. The HHS secretary's declaration of an emergency triggering an EUA specifies the CBRN agents and the products covered under the EUA.11 The FDA is required to publish notice of each EUA in the Federal Register. In making the decision to declare an emergency justifying an EUA, the HHS secretary reviews information submitted in support of the EUA and may consult an EUA work group of federal officials.6 One emergency declaration can support multiple EUAs.4

Issuance of the EUA
Once the HHS secretary has declared an emergency justifying the EUA, the FDA commissioner may issue the EUA after consultation with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) (if feasible and appropriate given the emergency) and upon meeting statutory and other criteria.

Requests for EUA—FD&C Act §564 does not address the precise processes and data requirements for requesting and reviewing an EUA for specific products. In a guidance document, the FDA anticipates EUA requests will be submitted by government agencies (e.g., CDC, DoD) or private entities (e.g., medical product manufacturers).2,6 The type and amount of information needed to support an EUA request depends on the nature of the declared emergency and the proposed product for which the EUA is requested.2,6 Types of information the FDA recommends to support an EUA request include, but are not limited to, a description of the product and its intended uses, rationale behind the product's use under an EUA, available safety and efficacy data, and proposed labeling and instructions for the product's use.2,6 The FDA reviews EUA requests on a case-by-case basis using the scientific data available at the time and the circumstances of the emergency.2,6

Criteria for EUA Authorization—The FDA will issue an EUA if the FDA commissioner finds all of the following:

- The CBRN agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition.
- Based on the scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition specified in the declaration of emergency or caused by another medical product to diagnose, treat, or prevent a disease or condition caused by the specified agent.
- The known and potential benefits outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life-threatening disease or condition that is the subject of the declaration.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.1,5,6

The FDA commissioner issues a letter that authorizes the EUA. The letter must state: (1) the diseases or conditions the product may be used to diagnose, prevent, or treat within the scope of the EUA; (2) the known and potential benefits of the product; (3) conclusions concerning the safety and potential effectiveness of the product; (4) an assessment of the available scientific evidence; and (5) required and additional conditions of authorization.1

Conditions of Authorization—The FDA may establish conditions on the use of a product under an EUA. For unapproved products, FD&C Act §564 requires the FDA commissioner (to the extent practicable given the circumstances of the emergency) to establish certain required conditions on an EUA that the commissioner finds necessary or appropriate to protect public health and permits the commissioner to establish other conditions that he or she finds necessary or appropriate to protect public health.2 Such conditions include:

- A requirement to disseminate information (e.g., fact sheets) to healthcare professionals or authorized dispensers and prospective patients or other consumers regarding the EUA, the product's significant known and potential benefits and risks, and the extent to which such benefits and risks are unknown.
- Available alternatives and their benefits and risks.
- For prospective patients and consumers, the option to accept or refuse the product, any consequences of refusal, and alternatives to the product.
- Other conditions such as restricted advertising, distribution, and administration; adverse event reporting and monitoring; data collection and analysis; recordkeeping and records access; and compliance with Current Good Manufacturing Practice (CGMP).2,6

For unapproved uses of approved products, certain of the above conditions as well as other conditions may be required in an EUA.2,6 These may include labeling requirements and the distribution of appropriate information in addition to label information.1

Duration and Termination—The EUA is in effect for one year from the date of issuance or for as long as the HHS secretary's §564 emergency declaration is in effect, whichever is shorter.1,5 The emergency declaration can be renewed. The EUA can be amended and may be revoked earlier if the criteria for issuance are no longer met or revocation is appropriate to protect public health or safety.6

Pre-EUA

Since EUA conditions are established when the EUA is issued, public health officials will not know all of the expected requirements of a particular authorization in advance of an emergency. As a result, state and local officials will have to comply with conditions for which they might not be able to effectively plan. While the law does not allow the FDA to preauthorize an EUA before the determination and declaration of an emergency, the process of requesting an EUA can begin before the actual emergency occurs.4 A "pre-EUA" request can be submitted to the FDA based on likely situations such as potential anthrax attacks or smallpox outbreaks.4 Planners speculate about what the emergency might be and the products that could be used in those situations.4 A pre-EUA allows the FDA to begin work on fact sheets and other documentation.4 If an emergency is declared and the EUA is formally requested, the FDA can conduct a final review of the pre-EUA materials and make any substantive changes as needed.4 The FDA will work with the states to ensure that any changes are included in final materials.4 Even without a pre-EUA, public health officials can begin planning based on the list of potential conditions identified by the FDA in its 2007 document Guidance—Emergency Use Authorization of Medical Products.6, 4

How the Law Affects States

States have been significantly impacted by the use of EUAs during emergencies. During H1N1, the FDA issued numerous EUAs—many more than in prior years—for antivirals, diagnostic devices, and N95 masks. The public's general concerns about perceived vaccine and drug safety issues also seemed to influence their views about medical products covered under EUAs. Healthcare professionals were unfamiliar with the EUA mechanism and how to use products authorized under it. Healthcare professionals and others dispensing EUA-authorized products were concerned about potential liability issues. However, EUA authority has provided an important legal mechanism to make medicines quickly available to respond to an emergency when their availability through regular FD&C Act/FDA processes might be delayed or be accompanied by burdensome procedures within the context of an emergency response.

Because of the relative newness of the EUA authority, public and private sector entities alike are still assessing the requirements for using EUA products and the liability protections available under the PREP Act when medical countermeasures are used under EUAs. States are encountering EUA products as part of the materiel deployed in the federal Strategic National Stockpile (SNS), as well as medicines that may have be granted extended expiration dates under the federal Shelf Life Extension Program (SLEP) (see ASTHO Fact Sheets on SNS and SLEP).

Practice Notes

- Understand the criteria under which an EUA can be issued and the conditions of authorization the FDA can place on use of EUA products.
- Understand the liability implications when using EUA products and the extent of PREP Act and other legal protections.
- Identify how your state plans to inform providers, the public, etc., about EUA products before and during an emergency.

EUAs Issued

- The Project BioShield Act granted EUA authority in 2004. Two EUAs were issued before 2009; one of these EUAs was for the Cities Readiness Initiative (CRI) Postal Model, which pre-positioned doxycycline tablets in emergency kits for USPS workers against inhalational anthrax.12
- Most of the EUAs have been issued in response to the 2009 H1N1 outbreak.
- In 2009 and 2010, EUAs were issued for 22 products including pandemic vaccines, antivirals, N95 respirators, and diagnostic tests.
- In 2011, FDA issued EUAs for the mass dispensing of doxycycline and the National Postal Model (NPM) (formerly the USPS CRI Postal Model).12
- As of December 2011, only two EUAs are in effect: (1) doxycycline for mass dispensing and (2) NPM kits.

Sources

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Note: This document was compiled from June–December 2011 and reflects the laws and programs current then. It reflects only portions of the laws relevant to public health emergencies and is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.

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U.S. FOOD & DRUG
ADMINISTRATION

February 25, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. On December 23, 2020, FDA reissued the December 11, 2020 letter to, among other revisions, remove reference to the number of doses per vial after dilution.[3]

On February 25, 2021, again having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the December 23, 2020, letter in its entirety with revisions incorporated to allow flexibility on the date of submission of monthly periodic safety reports and to revise the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers

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[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, in addition to removal of the reference to the number of doses per vial after dilution from the letter of authorization, FDA clarified the instructions for vaccination provider reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

Administering Vaccine (Vaccination Providers) is being revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers is being revised to add adverse reactions that have been identified during post authorization use.

Pfizer-BioNTech COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review has considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s)[5], to emergency response stakeholders[6] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[7] and used only to prevent COVID-19 in individuals ages 16 and older; and

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[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[5] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[6] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[7] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical

- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration.* 85 FR 79190 (December 9, 2020).

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 16 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the Pfizer COVID-19 Vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[8]

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;

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[8] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report. The first report is due July 2021.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational study(ies) to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (16 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The study(ies) should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

T. Vaccination providers administering Pfizer-BioNTech COVID-19 Vaccine must report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:
  - This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older; and
  - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

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DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *(see Storage and Handling)*.
- Refer to thawing instructions in the panels below.

Dilution

Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

- Refer to dilution and dose preparation instructions in the panels below.

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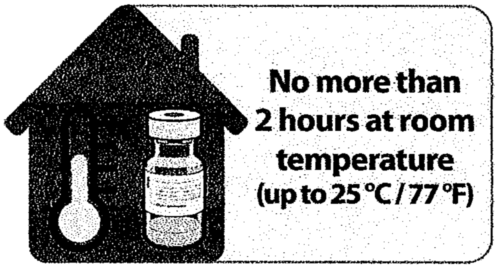
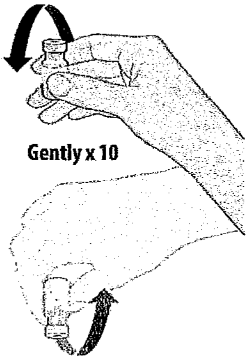
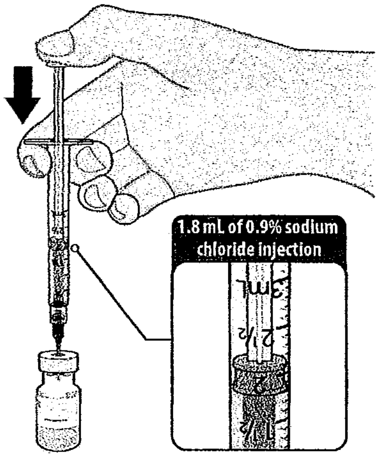
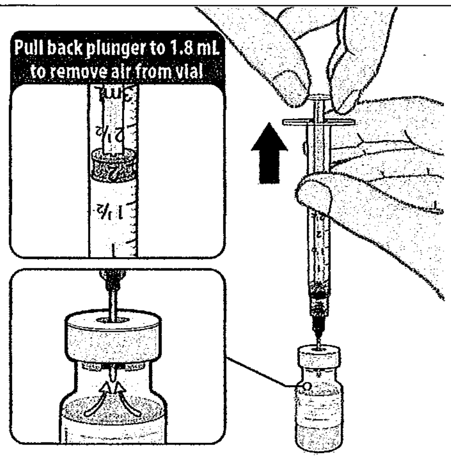
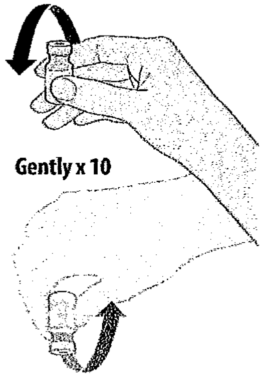
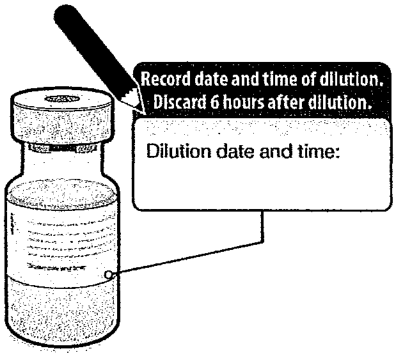
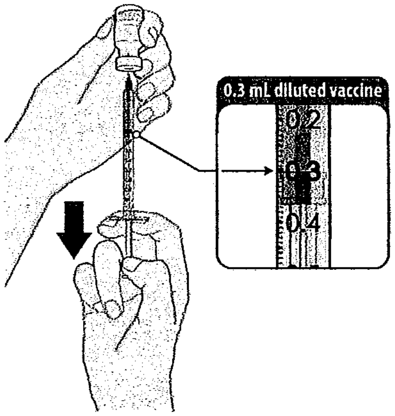
THAWING PRIOR TO DILUTION

 No more than 2 hours at room temperature (up to 25 °C / 77 °F)	- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). o Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. - Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	- Before dilution invert vaccine vial gently 10 times. - Do not shake. - Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. - Do not use if liquid is discolored or if other particles are observed.

DILUTION

 1.8 mL of 0.9% sodium chloride injection	- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. - Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). - Cleanse the vaccine vial stopper with a single-use antiseptic swab. - Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

 Pull back plunger to 1.8 mL to remove air from vial	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
 Record date and time of dilution. Discard 6 hours after dilution. Dilution date and time:	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Warnings

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy *(see Full EUA Prescribing Information).*

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;

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- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 16 years of age and older.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

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Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-1.0

Revised: December 2020

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

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* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *[see How Supplied/Storage and Handling (19)]*.
- Refer to thawing instructions in the panels below.

Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Refer to dilution and dose preparation instructions in the panels below.

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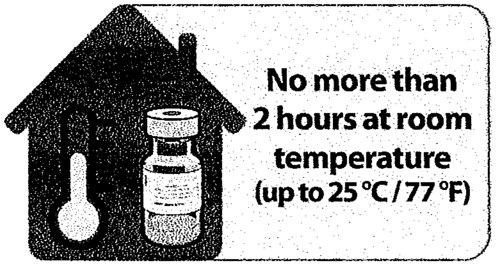
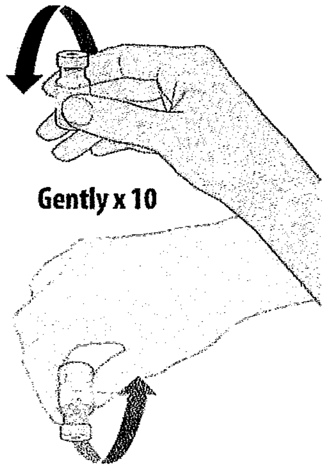
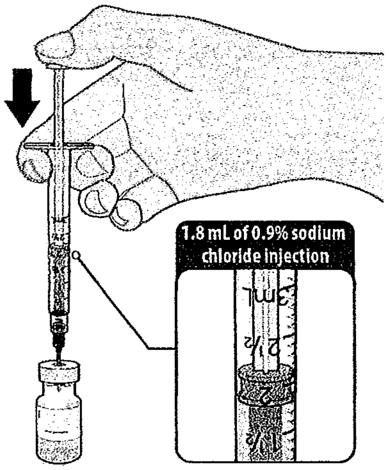
THAWING PRIOR TO DILUTION	
 No more than 2 hours at room temperature (up to 25 °C / 77 °F)	- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). o Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. - Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	- Before dilution invert vaccine vial gently 10 times. - Do not shake. - Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. - Do not use if liquid is discolored or if other particles are observed.
DILUTION	
 1.8 mL of 0.9% sodium chloride injection	- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. - Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). - Cleanse the vaccine vial stopper with a single-use antiseptic swab. - Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

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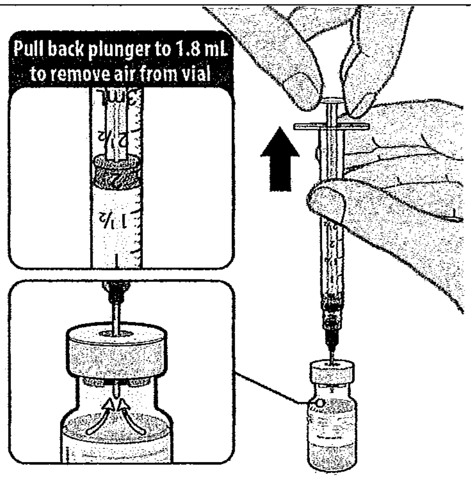
Pull back plunger to 1.8 mL to remove air from vial
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- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.

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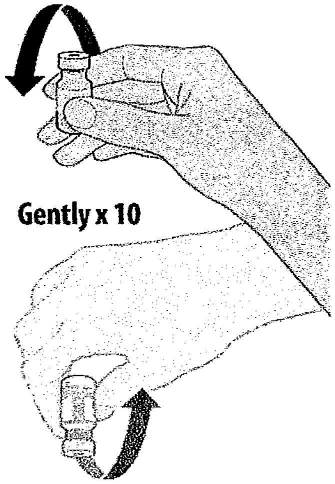

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- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

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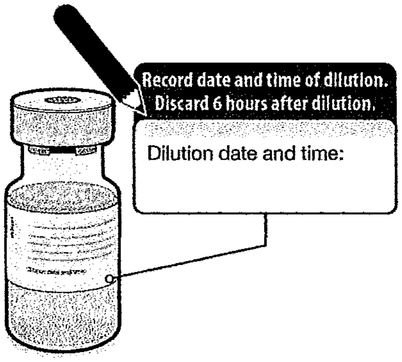
Record date and time of dilution. Discard 6 hours after dilution.

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- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 6 hours after dilution.

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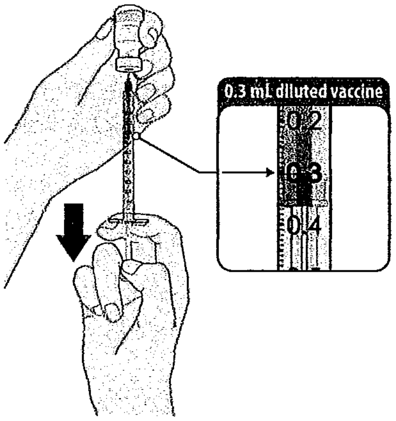
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine. - Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

2.3 Vaccination Schedule for Individuals 16 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.3 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 16 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 44,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively).

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older have been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020. Participants 18 years and older in the reactogenicity subset are monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo in the subset of participants 18 to 55 years of age included in the EUA safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo for participants 56 years of age and older.

Across both age groups, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age[‡] – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

‡ Eight participants were between 16 and 17 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age‡ – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache[c]				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N^a=2291 n^b (%)	Placebo Dose 1 N^a=2298 n^b (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N^a=2098 n^b (%)	Placebo Dose 2 N^a=2103 n^b (%)
Vomiting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication[f]	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Redness[c]				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling[c]				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Headache[c]				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills[c]				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting[d]				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea[e]				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain[c]				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 to 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7960, placebo = 7934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Overall in Study 2 in which 10,841 participants 16 to 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. The higher frequency of reported unsolicited non-serious adverse events among Pfizer BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.

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3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 16 and 17 years of age is based on extrapolation of safety and effectiveness from adults 18 years of age and older. Emergency Use Authorization of Pfizer BioNTech COVID-19 Vaccine does not include use in individuals younger than 16 years of age.

11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy *[see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)]*. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

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The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 5 presents the specific demographic characteristics in the studied population.

Table 5: Demographics (population for the primary efficacy endpoint)[a]

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	Placebo (N=18,379) n (%)
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[b]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[c]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

b. Includes multiracial and not reported.

c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease

- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index ≥ 30 kg/m^2)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

Efficacy Against COVID-19

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 to 55 years of age and 56 years of age and older began enrollment from July 27,2020, 16 to 17 years of age began enrollment from September 16, 2020 and 12 to 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 6.

Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

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d. n2 = Number of participants at risk for the endpoint.
e. No confirmed cases were identified in participants 12 to 15 years of age.
f. Credible interval for VE was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta=r(1\text{-}VE)/(1+r(1\text{-}VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2).

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light, in the original cartons, until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

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Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1457-1.0

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FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE?

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?

No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-1.0

Revised: December 2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

FDA U.S. FOOD & DRUG
ADMINISTRATION

February 25, 2021

ModernaTX, Inc.
Attention: Ms. Carlota Vinals
200 Technology Square
Cambridge, MA 02139

Dear Ms. Vinals:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 18, 2020, FDA issued an Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Act.

On February 25, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the December 18, 2020, letter in its entirety with revisions incorporated to allow flexibility on the date of submission of monthly periodic safety reports and to revise the requirements for reporting of vaccine administration errors by ModernaTX, Inc.

Moderna COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

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[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3,* 85 FR 18250 (April 1, 2020).

FDA reviewed safety and efficacy data from an ongoing phase 3 trial in approximately 30,000 participants randomized 1:1 to receive Moderna COVID-19 Vaccine or saline control. The trial has enrolled participants 18 years of age and older.

FDA's review of the available safety data from 30,351 participants 18 years of age and older, who were followed for a median of 7 weeks after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. Review of additional safety data from these participants with a median of 9 weeks of follow-up after receipt of the second dose did not change FDA's assessment of safety of the vaccine.

FDA's analysis of the efficacy data from 28,207 participants 18 years of age and older without evidence of SARS-CoV-2 infection prior to dose 1 confirms the vaccine was 94.1% effective (95% confidence interval (CI) 89.3, 96.8) in preventing COVID-19 occurring at least 14 days after the second dose (with 11 COVID-19 cases in the vaccine group compared to 185 COVID-19 cases in the placebo group). In this final scheduled analysis participants had been followed for a median of 9 weeks following the second dose. This result is consistent with that obtained from an interim analysis of efficacy conducted after these participants had been followed for a median of 7 weeks after the second dose (vaccine efficacy 94.5%, 95% CI: 86.5, 97.8).

Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on December 17, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Moderna COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- ModernaTX, Inc. will supply Moderna COVID-19 Vaccine either directly or through authorized distributor(s)[4] to emergency response stakeholders[5] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Moderna COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[6] and used only to prevent COVID-19 in individuals ages 18 and older; and
- The Moderna COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

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[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[4] "Authorized Distributor(s)" are identified by ModernaTX, Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Moderna COVID-19 Vaccine.

[5] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[6] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration.* 85 FR 79190 (December 9, 2020).

Product Description

The Moderna COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials.. The Moderna COVID-19 Vaccine does not contain a preservative.

Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains 100 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Moderna COVID-19 Vaccine also includes the following ingredients: lipids (SM-102; 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]; cholesterol; and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

The dosing regimen is two doses of 0.5 mL each, one month apart.

The manufacture of the authorized Moderna COVID-19 Vaccine is limited to those facilities identified and agreed upon in the ModernaTX, Inc. request for authorization.

The Moderna COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Moderna COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

The Moderna COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Moderna COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Moderna COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Moderna COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Moderna COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 18 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

ModernaTX, Inc. and Authorized Distributor(s)

A. ModernaTX, Inc. and authorized distributor(s) will ensure that the authorized Moderna COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. ModernaTX, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. ModernaTX, Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Moderna COVID-19 Vaccine. ModernaTX, Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. ModernaTX, Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. ModernaTX, Inc. may request changes to this authorization, including to the authorized Fact Sheets for Moderna COVID-19 Vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation[7].

F. ModernaTX, Inc. will report to Vaccine Adverse Event Reporting System (VAERS):

- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to ModernaTX, Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by ModernaTX, Inc.

G. ModernaTX, Inc. must submit to Investigational New Drug application (IND) number 19745 periodic safety reports at monthly intervals, in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE), beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:

- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

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[7] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

J. ModernaTX, Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. ModernaTX, Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report. The first report is due July 2021.

L. ModernaTX, Inc. and authorized distributor(s) will maintain records regarding release of Moderna COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. ModernaTX, Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. ModernaTX, Inc. will conduct post-authorization observational studies to evaluate the association between Moderna COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Moderna COVID-19 Vaccine under this EUA in the general U.S. population (18 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. ModernaTX, Inc. will provide protocols and status update reports to the IND 19745 with agreed-upon study designs and milestone dates.

O. ModernaTX, Inc., working with its contract research organization, will continue to monitor the performance of its clinical investigators in ongoing clinical studies of its vaccine and will report to FDA promptly any significant deviations from the protocols.

Emergency Response Stakeholders

P. Emergency response stakeholders will identify vaccination sites to receive authorized Moderna COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

Q. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

R. Emergency response stakeholders receiving authorized Moderna COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

S. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

T. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

U. Vaccination providers administering Moderna COVID-19 Vaccine must report the following information associated with the administration of Moderna COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words " Moderna COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to ModernaTX, Inc., by contacting 1-866-663-3762, by providing a copy of the VAERS form to ModernaTX, Inc., Fax: 1-866-599-1342 or by email; ModernaPV@modernatx.com.

V. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

W. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

X. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Z. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that:
  - This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and
  - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE,** for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the vial and carton labels.

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Storage Prior to Use

As Displayed on the Vial Labels and Cartons

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light.

Additional Storage Information Not Displayed on the Vial Labels and Cartons

Do not store on dry ice or below -40°C (-40°F).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.

Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-

19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5 mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *(see Full EUA Prescribing Information).*

WARNINGS

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. *(See Full EUA Prescribing Information)*

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES

There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID- 19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

    *Serious adverse events are defined as:
    - Death;
    - A life-threatening adverse event;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect;
    - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

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ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information.*

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are

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specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

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Patent(s): www.modernatx.com/patents
Revised: 12/2020

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION
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3 DOSAGE FORMS AND STRENGTHS
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*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain

white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,
- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Moderna COVID-19 Vaccine is administered as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse

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reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.3 Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID- 19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White,10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were Other, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected using standardized diary cards for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose by subject are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade 3[f]	219	553	162	129

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
	(1.9)	(5.0)	(1.4)	(1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[h] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[i] Grade 3 fever: Defined as ≥39.0 – ≤40.0°C / ≥102.1 – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

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Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo**[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting,	4	10	4	3

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Grade 3[g]	(0.1)	(0.3)	(0.1)	(<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[g] Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[h] Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.

[i] Grade 3 fever: Defined as $\geq$39.0– $\leq$40.0°C / $\geq$102.1 – $\leq$104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 2 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-Diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.

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2. In Box 18, description of the event:
    a. Write "Moderna COVID-19 Vaccine EUA" as the first line
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	**Fax number**	**Telephone number**
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary
All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically

recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development or postnatal development were reported in the study.

11.2 Lactation

Risk Summary
Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age *[see Clinical Trial Results and Supporting Data for EUA (18)]*. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants [see *Clinical Trials Experience (6.1)]*.

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set), included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were white, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

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Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	**COVID-19 Cases (n)**	**Incidence Rate of COVID-19 per 1,000 Person-Years**	**Participants (N)**	**COVID-19 Cases (n)**	**Incidence Rate of COVID-19 per 1,000 Person-Years**	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.

† VE and 95% CI from the stratified Cox proportional hazard model

The subgroup analyses of vaccine efficacy are presented in Table 4.

Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)*
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.

† VE and 95% CI from the stratified Cox proportional hazard model

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS, (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple-Dose Vials are supplied as a carton of 10 multiple-dose vials (NDC 80777-273-99).

Store frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light. Do not store on dry ice or below -40°C (-40°F).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	**Telephone number**
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most resent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

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Patent(s): www.modernatx.com/patents
Revised: 12/2020

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

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WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

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WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?

No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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Patent(s): www.modernatx.com/patents
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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

Hoja informativa para pacientes, padres y cuidadores
Autorización de uso de emergencia (EUA) de bamlanivimab para la enfermedad por coronavirus 2019 (COVID-19)

Le están administrando un medicamento llamado **bamlanivimab** para el tratamiento de la enfermedad por coronavirus 2019 (COVID-19). Esta hoja informativa contiene información de utilidad para comprender los riesgos y beneficios potenciales de tomar bamlanivimab, que puede recibir.

Recibir bamlanivimab puede beneficiar a ciertas personas afectadas de COVID-19.

Lea esta hoja informativa para saber más sobre el bamlanivimab. En caso de duda, consulte con su proveedor de atención sanitaria. Usted decide si quiere recibir bamlanivimab o dejar de tomarlo en cualquier momento.

¿Qué es la COVID-19?
La COVID-19 está causada por un virus llamado coronavirus. Las personas pueden contraer la COVID-19 a través del contacto con otra persona que tenga el virus.

Los trastornos causados por la COVID-19 varían entre muy leves (incluidas algunas personas sin síntomas notificados) y graves, incluidos trastornos que causan defunción. Si bien la información hasta el momento sugiere que la mayoría de los trastornos causados por la COVID-19 son leves, se pueden producir trastornos graves que podrían provocar el empeoramiento de sus otras afecciones médicas. Las personas de cualquier edad con afecciones médicas graves y de larga duración (crónicas) como cardiopatías, enfermedad pulmonar y diabetes, por ejemplo, parecen tener un mayor riesgo de ser hospitalizadas por la COVID-19.

¿Cuáles son los síntomas de la COVID-19?
Los síntomas de la COVID-19 incluyen fiebre, tos y dificultad para respirar, y pueden aparecer entre 2 y 14 días después de la exposición. Pueden producirse trastornos graves, incluidos problemas respiratorios, que podrían provocar el empeoramiento de sus otras afecciones médicas.

¿Qué es bamlanivimab?
El bamlanivimab es un medicamento en investigación que se utiliza para tratar los síntomas entre leves y moderados de la COVID-19 en adultos y adolescentes no hospitalizados (de 12 años o más que pesen al menos 88 libras (40 kg)), y que corran un alto riesgo de desarrollar síntomas graves por COVID-19 o de necesitar hospitalización. El bamlanivimab se encuentra en fase de investigación porque todavía se está estudiando. No se dispone de mucha información sobre la seguridad o la eficacia del uso de bamlanivimab para tratar a personas afectadas de COVID-19.

La Administración de Alimentos y Medicamentos de los Estados Unidos (FDA) ha autorizado el uso de emergencia de bamlanivimab para el tratamiento de la COVID-19 bajo una Autorización de Uso de Emergencia (EUA). Para obtener más información sobre la EUA, consulte la sección: **"¿Qué es una autorización de uso de emergencia (EUA)?"** que aparece al final de esta hoja informativa.

¿Qué debo decirle a mi profesional sanitario antes de recibir bamlanivimab?
Informe a su profesional sanitario sobre todas sus afecciones médicas, incluyendo lo siguiente:
- Si sufre alguna alergia
- Si está embarazada o tiene pensado quedarse embarazada
- Si está en período de lactancia o tiene pensado estarlo
- Si padece alguna enfermedad grave
- Si está tomando algún medicamento (con receta, de venta libre, vitaminas y productos a base de plantas medicinales).

¿Cómo recibiré bamlanivimab?
- Se le administrará bamlanivimab en vena (vía intravenosa o I.V.).
- Recibirá una dosis de bamlanivimab mediante infusión intravenosa. La infusión tardará entre 16 y 60 minutos o más. El profesional sanitario determinará la duración de la infusión.

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¿Cuáles son los posibles efectos secundarios importantes del bamlanivimab?

Los posibles efectos secundarios del bamlanivimab son:

- Reacciones alérgicas. Se pueden producir reacciones alérgicas durante y después de la infusión de bamlanivimab. Informe a su profesional sanitario de inmediato si tiene alguno de los siguientes signos y síntomas de reacciones alérgicas: fiebre, escalofríos, náuseas, dolor de cabeza, dificultad para respirar, presión arterial baja o alta, ritmo cardíaco alto o bajo, dolor o molestia en el pecho, debilidad, confusión, fatiga, sibilancias, hinchazón de los labios, cara o garganta, erupción cutánea, incluida la urticaria, picazón, dolor muscular, mareos y sudoración. Estas reacciones pueden ser graves o fatales.
- Síntomas de empeoramiento después de la administración de bamlanivimab: puede experimentar síntomas nuevos o que empeoran después de la infusión, entre los que se incluyen fiebre, dificultad para respirar, ritmo cardíaco alto o bajo, cansancio, debilidad o confusión. Si esto ocurre, comuníquese con su profesional sanitario o busque atención médica inmediata, ya que algunos de estos síntomas han requerido hospitalización. Se desconoce si están relacionados con la infusión de bamlanivimab o se deben a la progresión de la COVID-19.

Los efectos secundarios de recibir un medicamento por vía intravenosa pueden incluir dolor breve, sangrado, hematomas en la piel, molestias, hinchazón y posible infección en el lugar de la infusión.

Estos no son los únicos efectos secundarios posibles del bamlanivimab. Se ha administrado bamlanivimab a un número reducido de personas. Pueden producirse efectos secundarios graves e inesperados. El bamlanivimab todavía se encuentra en fase de estudio. Por ello, es posible que no se conozcan todos los riesgos asociados en este momento.

Es posible que el bamlanivimab pueda interferir con la capacidad propia del cuerpo de defenderse contra una infección porSARS-CoV-2 en el futuro. De igual modo, el bamlanivimab podría reducir la respuesta inmunitaria del cuerpo a una vacuna para elSARS-CoV-2. No se han realizado estudios específicos que aborden estos posibles riesgos. Consulte con su profesional sanitario en caso de duda.

¿Qué otras opciones de tratamiento existen?

Al igual que el bamlanivimab, la FDA puede permitir el uso de emergencia de otros medicamentos para tratar a las personas con la COVID-19. Consulte la página https://www.covid19treatmentguidelines.nih.gov/ para obtener información sobre el uso de emergencia de otros medicamentos que no están aprobados por la FDA para tratar a las personas con COVID-19. Es posible que su profesional sanitario hable con usted sobre los ensayos clínicos para los que podría ser idóneo.

Usted decide si quiere ser tratado o no con bamlanivimab. Si decide no recibir bamlanivimab o dejar de tomarlo en algún momento, esto no cambiará la atención médica que recibe habitualmente.

¿Qué ocurre si estoy embarazada o en período de lactancia?

Disponemos de muy poca experiencia en cuanto al tratamiento de mujeres embarazadas o en período de lactancia con bamlanivimab. Para la madre y el feto, el beneficio de recibir bamlanivimab podría ser superior al riesgo derivado del tratamiento. Si está embarazada o en período de lactancia, comente sus opciones y su situación específica con su profesional sanitario.

¿Cómo debo notificar los efectos secundarios del bamlanivimab?

Informe a su profesional médico de inmediato si tiene algún efecto secundario que le moleste o que no desaparezca.

Notifique los efectos secundarios a **FDA MedWatch** en la página www.fda.gov/medwatch, llame al 1-800-FDA-1088, o bien póngase en contacto con Eli Lilly and Company en el número1-855-LillyC19 (1-855-545-5921).

¿Cómo puedo obtener más información?

- Consulte con su proveedor de atención sanitaria

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- Visite la página www.bamlanivimab.com
- Visite la página https://www.covid19treatmentguidelines.nih.gov/
- Póngase en contacto con su departamento de salud pública local o estatal

¿Qué es una autorización de uso de emergencia (EUA)?
La FDA de los Estados Unidos ha puesto a disposición bamlanivimab bajo un mecanismo de acceso de emergencia llamado EUA. La EUA está respaldada por una declaración del Secretario de Salud y Servicios Humanos (HHS) sobre la existencia de circunstancias que justifican el uso de emergencia de medicamentos y productos biológicos durante la pandemia de la COVID-19.

El bamlanivimab no se ha sometido al mismo tipo de revisión que cualquier otro producto aprobado o autorizado por la FDA. La FDA puede emitir una EUA cuando se cumplen ciertos criterios, que incluyen que no haya alternativas adecuadas, aprobadas y disponibles. Además, la decisión de la FDA se basa en la totalidad de los datos científicos disponibles que muestran que es razonable creer que el producto cumple con ciertos criterios de seguridad, funcionamiento y etiquetado y que puede ser eficaz en el tratamiento de pacientes durante la pandemia de la COVID-19. Todos estos criterios deben cumplirse para que el producto pueda utilizarse en el tratamiento de pacientes durante la pandemia de la COVID-19.

La EUA para bamlanivimab permanecerá vigente mientras dure la declaración de la COVID-19 que justifica el uso de emergencia de estos productos, a menos que ésta se cancele o revoque (después de lo cual el producto ya no se podrá usar).

Datos revisados en enero de 28, 2021

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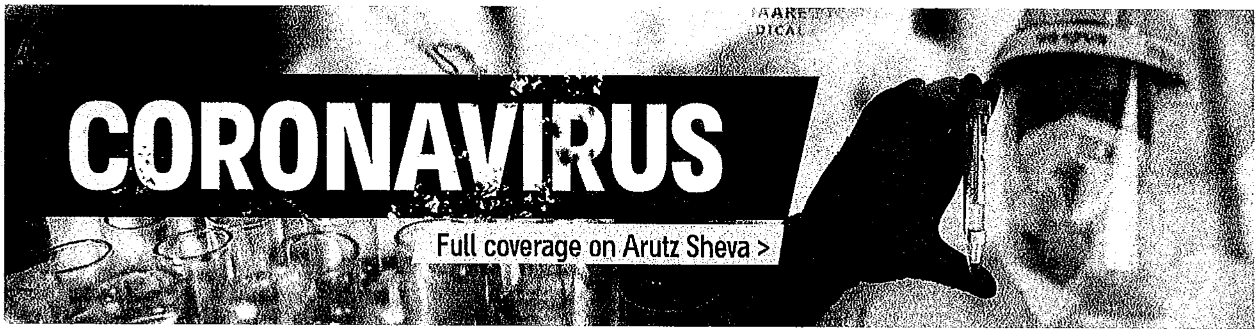
BAM-0002-EUA PAT-20210128


CORONAVIRUS
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Vaccination in Israel: Challenging mortality figures?

Analysis by infectious disease specialist claims mismatch between data published by authorities and reality on the ground.

Tags: Mortality Vaccination Biotechnology Israel Coronavirus

Mordechai Sones , Feb 18 , 2021 8:47 AM

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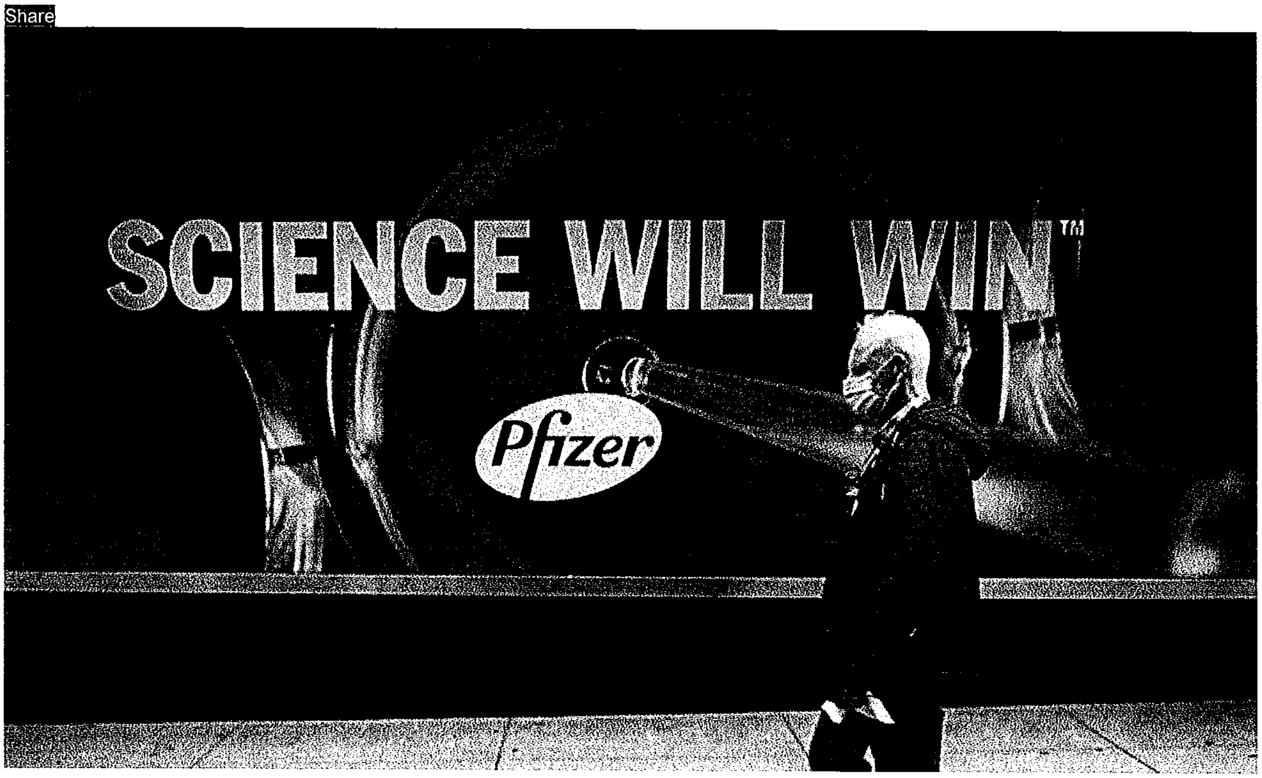
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Pfizer

'Science will win': Pfizer

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A front-page article appeared in the *FranceSoir* newspaper about findings on the *Nakim* website regarding what some experts are calling "the high mortality caused by the vaccine."

The paper interviews Aix-Marseille University Faculty of Medicine Emerging Infectious and Tropical Diseases Unit's Dr. Hervé Seligmann and engineer Haim Yativ about their research and data analysis. They claim that Pfizer's shot causes "mortality hundreds of times greater in young people compared to mortality from coronavirus without the vaccine, and dozens of times more in the elderly, when the documented mortality from coronavirus is in the vicinity of the vaccine dose, thus adding greater mortality from heart attack, stroke, etc."

Dr Hervé Seligmann works at the Emerging Infectious and Tropical Diseases Research Unit, Faculty of Medicine, Aix-Marseille University, Marseille, France. He is of Israeli-Luxembourg nationality. He has a B. Sc. In Biology from the Hebrew University of Jerusalem, and has written over 100 scientific publications.

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FranceSoir writes that they follow publications, data analyzes, and feedback from various countries on vaccination, and have therefore taken an interest in the *Nakim* article, asking to interview them in order to understand their analysis and its limitations.

The authors of the article declare they have no conflicts or interests other than having children in Israel.

After a presentation, the authors discussed their data analysis, the validations carried out, limitations, and above all, their conclusions that they compare with data received via a Health Ministry Freedom of Information Act request.

Their findings are:

- There is a mismatch between the data published by the authorities and the reality on the ground.
- They have three sources of information, besides the emails and adverse event reports they receive through the Internet. These three sources are Israeli news

site *Ynet*, the Israeli Health Ministry database, and the U.S. federal Vaccine Adverse Event Reporting System (**VAERS**) database.

- In January 2021, there were 3,000 records of vaccine adverse events, including 2,900 for mRNA vaccines.
- Compared to other years, mortality is 40 times higher.
- On February 11, a *Ynet* article presented data related to vaccination. The authors of the *Nakim* article claim to have debunked this analysis based on data published by *Ynet* itself: "We took the data by looking at mortality during the vaccination period, which spans 5 weeks. By analyzing these data, we arrived at startling figures that attribute significant mortality to the vaccine."
- The authors say "vaccinations have caused more deaths than the coronavirus would have caused during the same period."
- Haim Yativ and Dr. Seligmann declare that for them, "this is a new Holocaust," in face of Israeli authority pressure to vaccinate citizens.

They also invite specialists to complete their analyses, and intend to pursue legal follow-up to their discovery. The Health Ministry was not available for comment on a *FranceSoir* query regarding the findings.

The authors also deplored "the fact of not being able to communicate on this vital information" to their fellow citizens.

On their site, *Nakim* writes: "On February 11, 2021, *Ynet* (the most known Israeli News website) published a confused and confusing article entitled '*Vaccination efficiency data in Israel, and its rapid effects on the young*'.

"Our reanalyses of these data explain why during the massive vaccination project initiated mid-December 2020 during a confinement, daily new confirmed COVID-19 cases failed to decrease as they do during confinements, and, more importantly, why numbers of serious, critical, and death cases increased during that period that covered at least one month. From mid-December to mid-February (two months), 2,337 among all Israeli 5,351 official COVID-deaths occurred. Our analyses indicate orders of magnitude increases in deaths rates during the 5-week long vaccination process, as compared to the unvaccinated and those after completing the vaccination process. Presumably, asymptomatic cases before vaccination, and those infected shortly after the 1st dose, tend to develop graver symptoms than those unvaccinated.

"The *Ynet* article is organized in an exciting way and uses data provided in an erroneous way by the Ministry of Health. It is unclear whether this was intentional to prove the vaccine's efficiency or if this was done erroneously because the provided data were misunderstood. Note that in Israel, all vaccines are from Pfizer.

"The data in the table, rather than indicating the vaccine efficacy, indicate the vaccine's adverse effects," the authors conclude.

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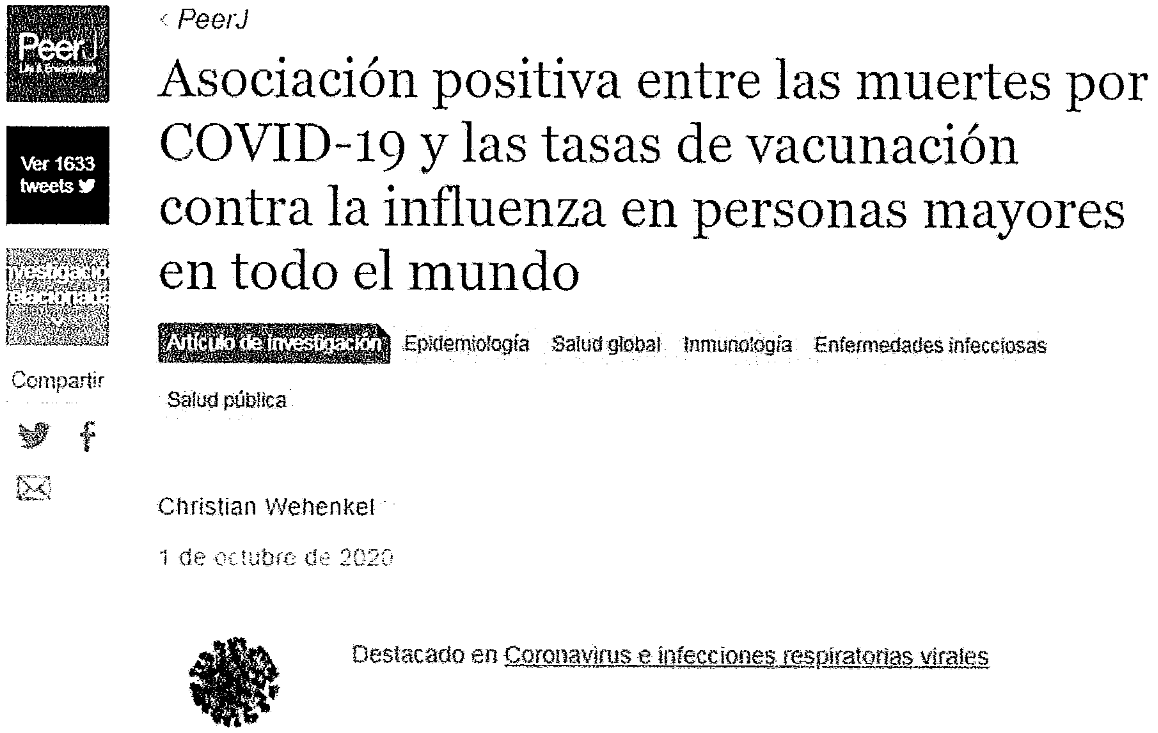
ASOCIACIÓN POSITIVA ENTRE LAS MUERTES POR COVID-19 Y LA VACUNA CONTRA LA INFLUENZA


PeerJ
Ver 1633 tweets
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Artículo de investigación
Epidemiología
Salud global
Inmunología
Enfermedades infecciosas
Salud pública

‹ *PeerJ*

Asociación positiva entre las muertes por COVID-19 y las tasas de vacunación contra la influenza en personas mayores en todo el mundo

Christian Wehenkel

1 de octubre de 2020

Destacado en Coronavirus e infecciones respiratorias virales

https://doi.org/10.7717/peerj.10112

Asociación positiva entre las muertes por COVID-19 y la vacuna contra la influenza – Dra. María José Martínez Albarracín Parte I –

Compartir link del video: https://www.bitchute.com/video/IJWLfHhSRHkh/

Dra. María José Martínez Albarracín, Efectos Adversos de la Vacuna COVID-19 Parte II – Compartir link del video:

https://www.bitchute.com/video/wHxaYMsJ5xtI/

Asociación positiva entre las muertes por COVID-19 y la vacuna contra la influenza

Wehenkel C. 2020 . Asociación positiva entre las muertes por COVID-19 y las tasas de vacunación contra la influenza en personas mayores en todo el mundo . ***PeerJ*** **8 : e10112 https://doi.org/10.7717/peerj.10112**

El objetivo de este estudio fue analizar la asociación entre las muertes relacionadas con COVID-19 y la tasa de vacunación contra la influenza (IVR Influenza Vaccination Rate) en personas mayores en todo el mundo.

Se analizaron los conjuntos de datos disponibles de países con más de 0,5 millones de habitantes (en total 39 países). Para estimar con precisión la tasa de vacunación contra la influenza en las muertes por COVID-19 y mitigar los efectos de las variables de confusión, se realizó una clasificación sofisticada de la importancia de diferentes variables. Las asociaciones se midieron mediante coeficientes de correlación de rango de Spearman no paramétricos y funciones aleatorias.

Resultados

Los resultados mostraron una asociación positiva entre las muertes por COVID-19 y la la tasa de vacunación contra la influenza, IVR de personas mayores de 65 años. Trabajo adicional en esta línea de investigación puede conducir a la prevención de muertes asociadas con COVID-19.

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Interferencia inmunológica entre los polisorbatos parenterales y los virus como posible causa de la pandemia por coronavirus

Juan F. Gastón Añaños; Elisa M.ª Sahún García; Ana Martínez Giménez

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Se estudia la posible **relación entre la vacunación antigripal de la campaña 2019-2020 y la frecuencia relativa de muertes por COVID-19**, encontrándose que la administración de la vacuna antigripal adyuvada podría estar asociada a un **riesgo 6 veces mayor de fallecimiento por COVID-19 en mayores de 65 años**.

Dado que en la composición de esa vacuna se encuentran los polisorbatos, sustancias con antecedentes tóxicos conocidos, se plantea la hipótesis de que la mayor tasa de fallecimientos por COVID-19 podría ser consecuencia de un efecto adverso de los polisorbatos parenterales.

Se discute la conocida capacidad de los polisorbatos parenterales de alterar significativamente las membranas celulares como posible causa de una interferencia en la capacidad de las C-lectinas del endotelio vascular de unirse a los virus nuevos como primer paso para su posterior eliminación, con el consiguiente fracaso de la inmunidad innata frente a los coronavirus y la consiguiente facilitación de su infección.

Descargar estudio

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La vacuna de la gripe y el Covid-19

Doctora María José Martínez Albarracín

Hay varios estudios como este de los profesionales sanitarios del hospital de Barbastro o los del biólogo Bartomeu Payeras sobre la innegable correlación entre vacuna antigripal y gravedad o muerte por Covid.

También quiero citar otros dos, uno de **Home Vaccine Education Network:** ***"La vacuna de la gripe y el covid-19"*** traducido en Archivos editorial Cauac nativa el 30 sep. 2020. Y el otro: ***COVID-19 severity in Europe and the USA: Could the seasonal influenza vaccination play a role?*** de EBMPHET Consortium.

Todos ellos demuestran una correlación entre la gravedad y mortalidad por COVID y la vacunación antigripal, de manera que en los países donde ha habido mayor cobertura de esta vacunación en los años anteriores es donde más muertes se han producido. Esto se da también en España, si se hace el estudio por comunidades autónomas. Además, los casos se disparan cuando se sobrepasa un determinado umbral **(umbral de percolación)** que para la población adulta está en torno al 50% de cobertura vacunal.

Por otra parte el fenómeno no es nuevo, pues ya se observó en el año 2009 después de la pandemia de la gripe A:
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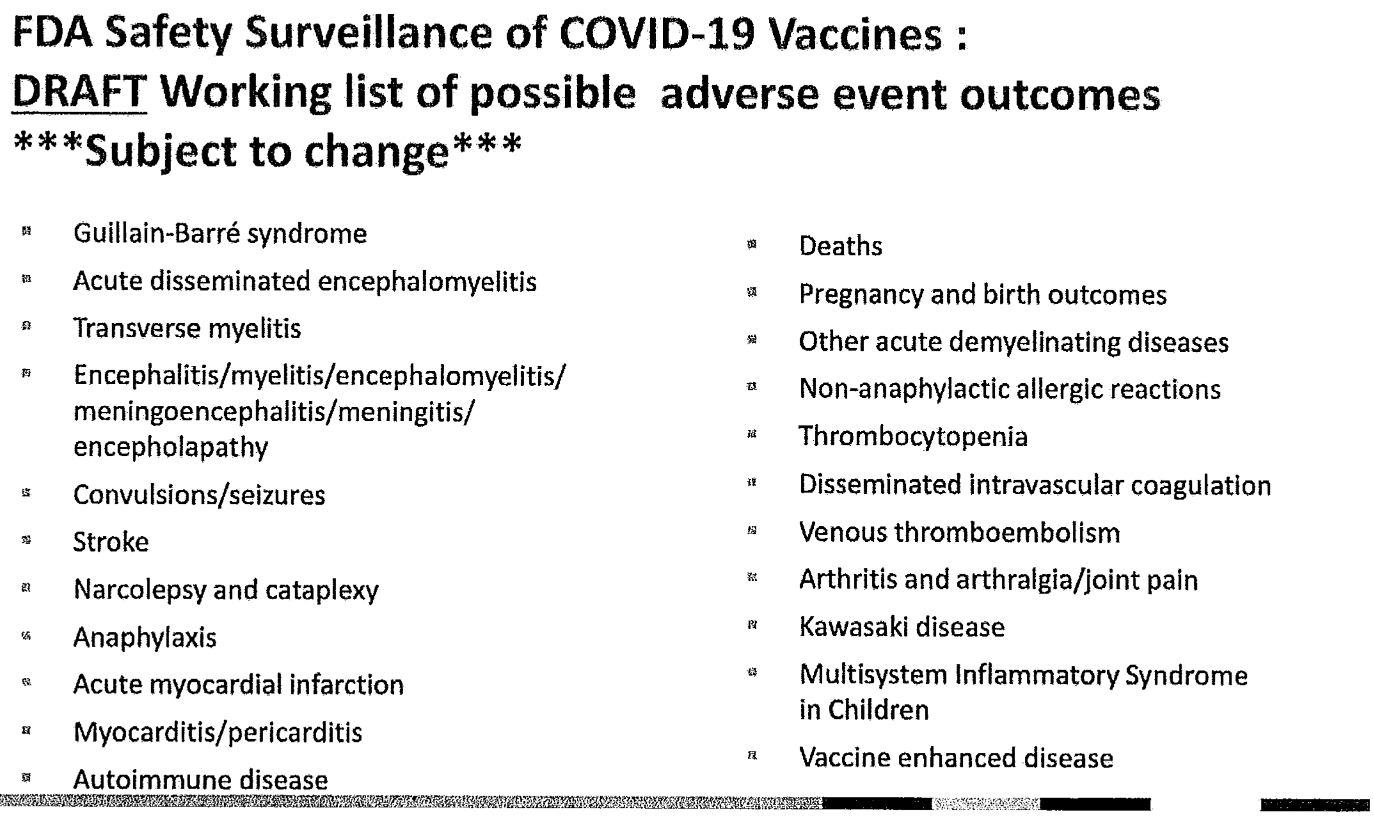
Association between the 2008–09 Seasonal Influenza Vaccine and Pandemic H1N1 Illness during Spring–Summer 2009: Four Observational Studies from Canada

Es bien sabido que la vacuna contra la gripe apenas supone ventaja epidemiológica, pues no disminuye ni las hospitalizaciones ni las muertes debidas a las epidemias anuales según se demuestra en revisiones y metaanálisis (Cochrane.Org). Esto debería ser suficiente para proponer una moratoria de dicha vacunación mientras se investigan las posibles relaciones causales, pero en vez de ello, este año el Ministerio de Sanidad y las Consejerías de Sanidad de las diferentes CCAA se han lanzado a una desaforada campaña propagandística para aumentar la cobertura vacunal antigripal, **sobre todo de los mayores de 65 años**, hasta conseguir el 75% de dicha cobertura. Así que, estaremos atentos a lo que pueda ocurrir, sobre todo a partir de enero que es cuando todos los años se produce el mayor pico de la epidemia de gripe.

Se está viendo también actualmente que en las personas que sufrieron Covid en primavera hay un cierto número de pacientes en los que han persistido diversas secuelas compatibles con síndromes autoinmunes. Como dicha autoinmunidad puede estar relacionada con las vacunaciones y revacunaciones antigripales (los antígenos vacunales ya no son naturales sino reordenados artificialmente, lo que supone un cierto tipo de **transgénesis**) y la misma Covid-19 se puede considerar en muchos aspectos un síndrome autoinmune, el más elemental **PRINCIPIO DE PRECAUCIÓN**, debería aconsejar una moratoria de dicha vacuna.



FDA Safety Surveillance of COVID-19 Vaccines :
DRAFT Working list of possible adverse event outcomes
Subject to change

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

Center for Biologics Evaluation and Research Plans for Monitoring COVID-19 Vaccine Safety

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Colaboración Cochrane: Vacunas contra la influenza sin beneficio

Cada temporada de invierno se aconseja a muchos, incluso se les presiona, para que se vacunen contra la gripe. Las vacunas contra la gripe se venden en todas las cadenas de farmacias ...
Pero, ¿qué muestra la evidencia sobre la eficacia de la vacuna contra la gripe cuando se comparan los grupos vacunados y no vacunados?

Bueno, el hallazgo de una revisión integral de **50 informes publicados** por la Colaboración Cochrane debería disuadir a las personas sanas de vacunarse contra la gripe:

> *"Los resultados de esta revisión parecen desalentar la utilización de la vacunación contra la influenza en adultos sanos como una medida de salud pública de rutina.*
> *Dado que los adultos sanos tienen un riesgo bajo de complicaciones debido a enfermedades respiratorias, el uso de la vacuna solo puede recomendarse como medida de protección individual contra los síntomas en casos específicos "*.

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001269.pub4/full

- Específicamente, la evidencia refuta las afirmaciones de que la vacuna contra la influenza previene la influenza;
- La evidencia refuta la afirmación de que previene la transmisión viral en adultos sanos;
- y la evidencia refuta la afirmación de que la vacuna previene complicaciones y "salva vidas".
- La evidencia muestra poco o ningún beneficio para las vacunas contra la influenza.

> *"Esta revisión incluye 15 de los 36 ensayos financiados por la industria (cuatro no tenían declaración de financiamiento). Una revisión sistemática anterior de 274 estudios de vacunas contra la influenza publicados hasta 2007 encontró que:*

- **"... los estudios financiados por la industria se publicaron en revistas más prestigiosas y se citaron más que otros estudios ..."**
- **"... la evidencia confiable sobre las vacunas contra la influenza es escasa ..."**
- **"... hay evidencia de una manipulación generalizada de las conclusiones ..."**

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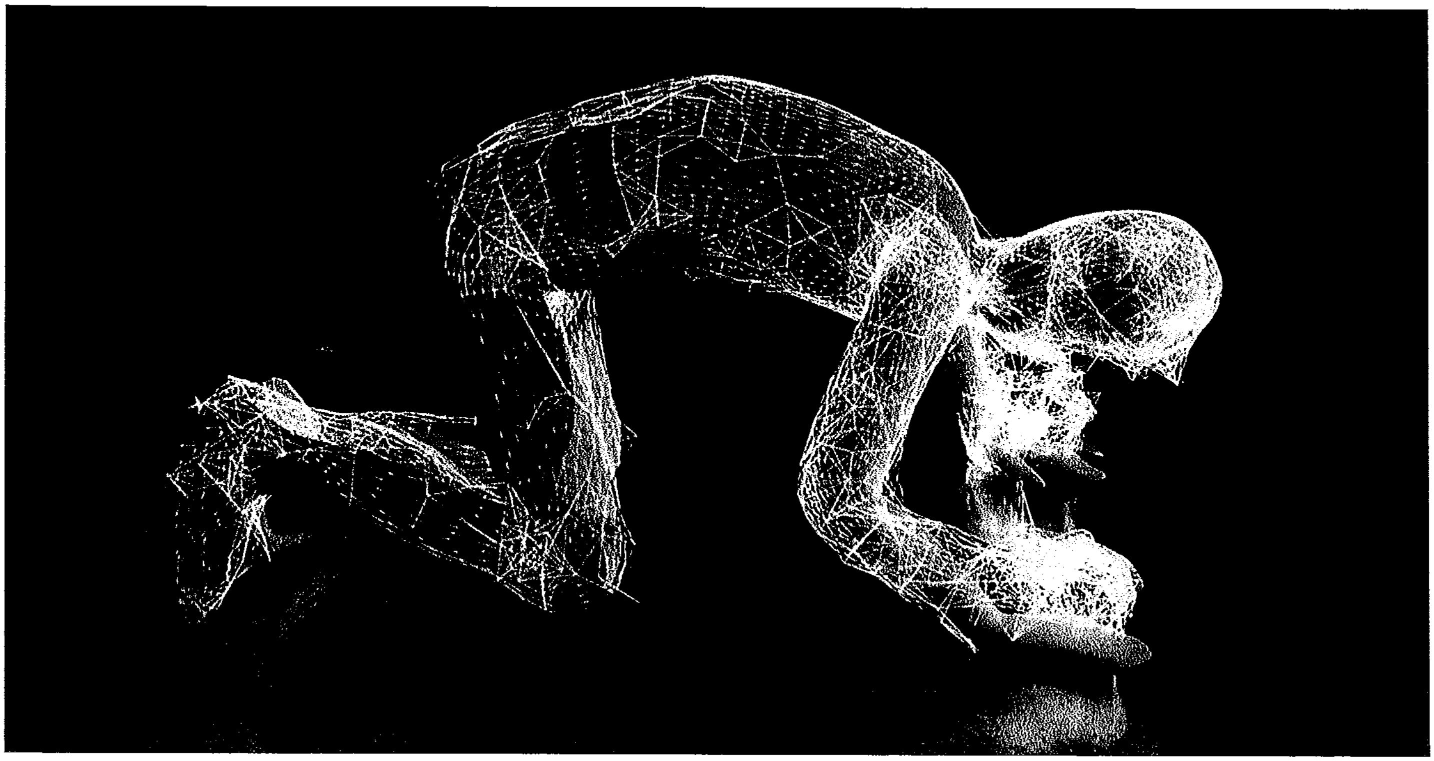
¿Hay relación entre la vacuna contra la influenza y la mortalidad por COVID-19?
CienciaySaludNatural.com

¿Hay relación entre la vacuna contra la influenza y la mortalidad por COVID-19?

Un ensayo aleatorizado con placebo en niños demostró que la vacuna contra la influenza aumentó 5 veces el riesgo de infecciones respiratorias agudas causadas por un grupo de virus que no son de influenza, incluidos los coronavirus.

CienciaySaludNatural.com

70.000 AFECTADOS POR LA INYECCIÓN EXPERIMENTAL EN INGLATERRA



El gobierno del Reino Unido ha publicado un informe que expone las reacciones adversas tanto de la inyección de Pfizer como la de Oxford / Astrazeneca que se han producido desde que comenzó el lanzamiento el 8 de diciembre. Ya hubieron más de 70.000 eventos adversos con la inyección contra C.O.V-I.D en Inglaterra, 1 de cada 333 personas están sufriendo reacciones adversas

El informe ha recopilado datos ingresados hasta el 24 de enero de 2021 a través del Programa de Tarjeta Amarilla de la "Medicines and Healthcare products Regulatory Agency", MHRA de Inglaterra. Ya se habían administrado aproximadamente 5.4 millones de primeras dosis de la vacuna Pfizer / BioNTech y 1.5 millones de dosis de la vacuna de la Universidad de Oxford / AstraZeneca, y se habían administrado alrededor de 0.5 millones de segundas dosis, principalmente la vacuna Pfizer / BioNTech.

Con el aumento de las vacunas administradas, se produjo un aumento en las reacciones adversas con 49.472 reacciones reportadas a la vacuna Pfizer y 21.032 reacciones a la vacuna Oxford / Astrazeneca. Para ambas vacunas, **esto equivale a 1 de cada 333 personas que sufren una reacción adversa**. En realidad, esta tasa podría ser más alta ya que es posible que algunos casos no se hayan notificado al Sistema de Tarjeta Amarilla.

Ver informe (click aquí) que tiene una revisión en profundidad de las reacciones a la vacuna Pfizer en donde se encontró que:

La inyección de Pfizer, que utiliza tecnología de ARNm para instruir a las células humanas para que produzcan la proteina de la espícula del Sars Cov 2", 5 personas hasta ahora han quedado ciegas y otras 31 han tenido problemas de visión. En total, se han notificado hasta ahora 634 trastornos oculares.

Cuadro tomado del Informe del Gobierno

También se han producido 21 accidentes cerebrovasculares gracias a la vacuna experimental Pfizer. Un accidente cerebrovascular es la muerte súbita de algunas células cerebrales debido a la falta de oxígeno cuando el flujo sanguíneo al cerebro se ve afectado por el bloqueo o la ruptura de una arteria del cerebro. Un accidente cerebrovascular también se conoce como accidente cerebrovascular.

Cuadro tomado del Informe del Gobierno

En diciembre el gobierno del Reino Unido admitió que no sabía si la inyección de Pfizer tenía un impacto en la fertilidad, lo que realmente debió haber convencido a los aspirantes a padres de no recibir la vacuna. Pero esa admisión también incluyó comentarios sobre el embarazo que fueron los siguientes:

Embarazo

No hay datos o son limitados sobre el uso de la vacuna de ARNm de COVID-19 BNT162b2. **No se han completado los** estudios de toxicidad reproductiva en animales . COVID-19 ARNm **Vacuna BNT162b2 no se recomienda durante el embarazo.** Para las mujeres en edad fértil, se debe excluir el embarazo antes de la vacunación. Además, se debe advertir a las mujeres en edad fértil que **eviten el embarazo durante al menos 2 meses después de** su segunda dosis.

Apoye a el periodismo independiente con fuentes sólidas, contribuya aqui:

Fuentes:

Pfizer
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/958616/COVID-19_mRNA_Pfizer-_BioNTech_Vaccine_Analysis_Print.pdf

AstraZeneca
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/958615/COVID-19_AstraZeneca_Vaccine_Analysis_Print.pdf

Coronavirus vaccine – summary of Yellow Card reporting
https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

Sudáfrica suspende aplicación de vacuna de AstraZeneca; estudio muestra que ofrece menos protección contra variante de covid-19 https://cnnespanol.cnn.com/2021/02/08/sudafrica-suspende-aplicacion-de-vacuna-de-astrazeneca-estudio-muestra-que-ofrece-menos-proteccion-contra-variante-de-covid-19/

a

Pfizer withdraws application for emergency use of its Covid vaccine in India
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/pfizer-withdraws-application-for-emergency-use-of-its-covid-vaccine-in-india/articleshow/80701405.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

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PMID: 32461193

Potential antigenic cross-reactivity between SARS-CoV-2 and human tissue with a possible link to an increase in autoimmune diseases

Aristo Vojdani[a,b,*] and Datis Kharrazian[b,c]

[a]Immunosciences Lab, Inc, 822 S. Robertson Blvd, Ste. 312, Los Angeles, CA 90035, USA
[b]Department of Preventive Medicine, Loma Linda University, Loma Linda, CA 92350, USA
[c]Harvard Medical School, 25 Shattuck St, Boston, MA 02115, USA
Aristo Vojdani: drari@msn.com; Datis Kharrazian: datis56@gmail.com
*Corresponding author at: Immunosciences Lab, Inc, 822 S. Robertson Blvd, Ste. 312, Los Angeles, CA 90035, USA. drari@msn.com

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Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website. Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

Since the outbreak of COVID-19 caused by SARS-CoV-2, we tested 5 different blood specimens that were confirmed positive for SARS-CoV-2.IgG and IgM antibodies [1]. The measurements were for anti-nuclear antibody (ANA), anti-extractable nuclear antigen (ENA), anti-double-stranded DNA (dsDNA), actin antibody, mitochondrial antibody, rheumatoid factor (RF), and C1q immune complexes. We were surprised to find out that 3 of the 5 specimens had significant elevations in ANA, ENA, actin and mitochondrial antibodies, but not against dsDNA or RF. This prompted us to investigate patterns of cross-reactivity between SARS-CoV-2 and autoimmune target proteins.

Vaccine-induced autoimmunity from autoimmune cross-reactivity is associated with narcolepsy, Guillain-Barré syndrome, multiple sclerosis, demyelinating neuropathies, systemic lupus erythematosus, and postural orthostatic tachycardia syndrome in susceptible subgroups as reported by Segal and Shoenfeld [2]. Due to the significant red flags for the potential cross-reactive interactions with the current COVID-19 pandemic, we studied the relationships between spike and nuclear proteins of SARS-CoV-2 and autoimmune target proteins.

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Commercially available mouse monoclonal antibody made against recombinant SARS coronavirus spike protein and rabbit monoclonal antibody made against SARS coronavirus nucleoprotein were applied at optimal dilution to the SARS-CoV-2 proteins and to 50 different tissue antigens using enzyme-linked immunosorbent assay (ELISA). Recombinant SARS-CoV-2 spike protein S1 and recombinant SARS-CoV-2 nucleocapsid protein were purchased from RayBiotech. ELISA wells were coated with nuclear antigens, dsDNA, F-actin, and mitochondria (M2) antigen purchased from different companies. An additional 45 tissue antigens used in this study have been previously described [9]. Each SARS-CoV-2 antibody was applied to quadruplicate wells. After the completion of all ELISA steps, the developed color was measured at 405 nm.

Looking at the reaction between SARS-CoV-2 spike protein antibody and tissue proteins (Fig. 1A), we found that the strongest reactions were with transglutaminase 3 (tTG3), transglutaminase 2 (tTG2), ENA, myelin basic protein (MBP), mitochondria, nuclear antigen (NA), α-myosin, thyroid peroxidase (TPO), collagen, claudin 5+6, and S100B. The reaction of this antibody was not as strong with several other antigens (Fig. 1A).

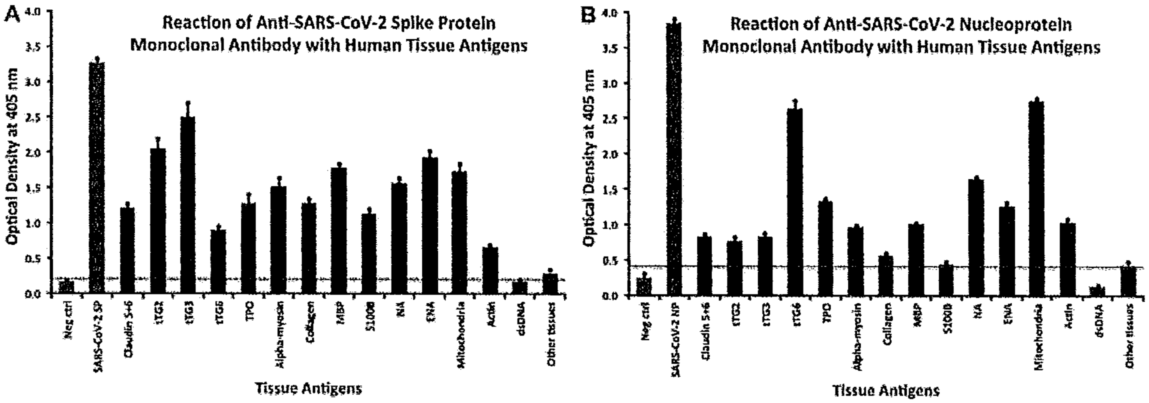

Fig. 1

(A) Reaction of anti-SARS-CoV-2 spike protein monoclonal antibody with human tissue antigens. (B) Reaction of anti-SARS-CoV-2 nucleoprotein monoclonal antibody with human tissue antigens.

The nucleoprotein antibody showed some overlap in immune cross-reactivity with anti-spike protein antibody. As shown in Fig. 1B, nucleoprotein antibody reacted strongly with mitochondria, tTG6, NA, TPO, ENA, TG, actin, and MBP. Similar to spike protein, the nucleoprotein antibody reaction was not as strong with several other antigens as shown in Fig. 1A and B.

As the number of SARS-CoV-2 infections increase from day to day, scientists are learning that the damage caused by this virus can extend well beyond the lungs, where infection can lead to pneumonia and the often fatal condition called acute respiratory distress syndrome [3]. The virus can in fact affect the body from head to toe, including the nervous [4], cardiovascular [5], immune [6], and digestive systems [7].

Is it possible that some of the extensive organ, tissue, and cellular damage done by SARS-CoV-2 is due to viral antigenic mimicry with human tissue?

If the answer is yes, then we may face an increase in the rates of autoimmune disease in the future, because any factor that causes chronic inflammation in the body can potentially induce autoimmune disease.

Because SARS-CoV-2 attacks the respiratory system first, in a very interesting letter [8] Kanduc and Shoenfeld suggested that because the SARS-CoV-2 spike glycoprotein and lung surfactant proteins shared 13 out of 24 pentapeptides, the immune response following infection with SARS-CoV-2 may lead to cross-reactions with pulmonary surfactant proteins, followed by SARS-CoV-2-associated lung disease [8]. Based on their findings, they warned against the use of the entire SARS-CoV-2 antigens in the vaccines and cautioned that perhaps the use of only unique peptides would be the most effective way to fight the SARS-CoV-2 infection. Very similar suggestions were made by Razim et al., in designing a vaccine against *Clostridium difficile* [9]. Two sequences, peptide 9 and peptide 10, of *C. difficile* were recognized not only by the sera of patients with *C. difficile* infections but also by the sera of patients with autoimmune disease. Razim et al. concluded that before considering a protein as a vaccine antigen, special care should be taken in analyzing the sequence of tissue cross-reactive epitopes in order to avoid possible future side effects [9].

We agree with Razim et al., and we feel that our own findings that 21 out of 50 tissue antigens had moderate to strong reactions with the SARS-CoV-2 antibodies are a sufficiently strong indication of cross-reaction between SARS-CoV-2 proteins and a variety of tissue antigens beyond just pulmonary tissue, which could lead to autoimmunity against connective tissue and the cardiovascular, gastrointestinal, and nervous systems.

We live in critical times when the world may be veering towards the very real possibility of requiring immunity certification "passports" earned by prior infection with SARS-CoV-2 or vaccination before being allowed to travel, or perhaps even to work [10].

At the moment, scientists are frantically trying to develop either a definitive cure, neutralizing antibodies, or a vaccine to protect us from contracting the disease in the first place, and they want it right now. We must consider that finding a vaccine for a disease may normally take years. There are reasons for all the precautions involved in developing a vaccine, not the least of which are unwanted side-effects. In light of the information discussed above about the cross-reactivity of the SARS-CoV-2 proteins with human tissues and the possibility of either inducing autoimmunity, exacerbating already unhealthy conditions, or otherwise resulting in unforeseen consequences, it would only be prudent to do more extensive research regarding the autoimmune-inducing capacity of the SARS-CoV-2 antigens. The promotion and implementation of such an aggressive "immune passport" program worldwide in the absence of thorough and meticulous safety studies may exact a monumental cost on humanity in the form of another epidemic, this time a rising tide of increased autoimmune diseases and the years of suffering that come with them.

Funding

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Declaration of Competing Interest

None.

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Irish Government Admits: COVID-19 Does NOT Exist

Published on December 26, 2020

Written by Gemma O'Doherty

nothing to
see here

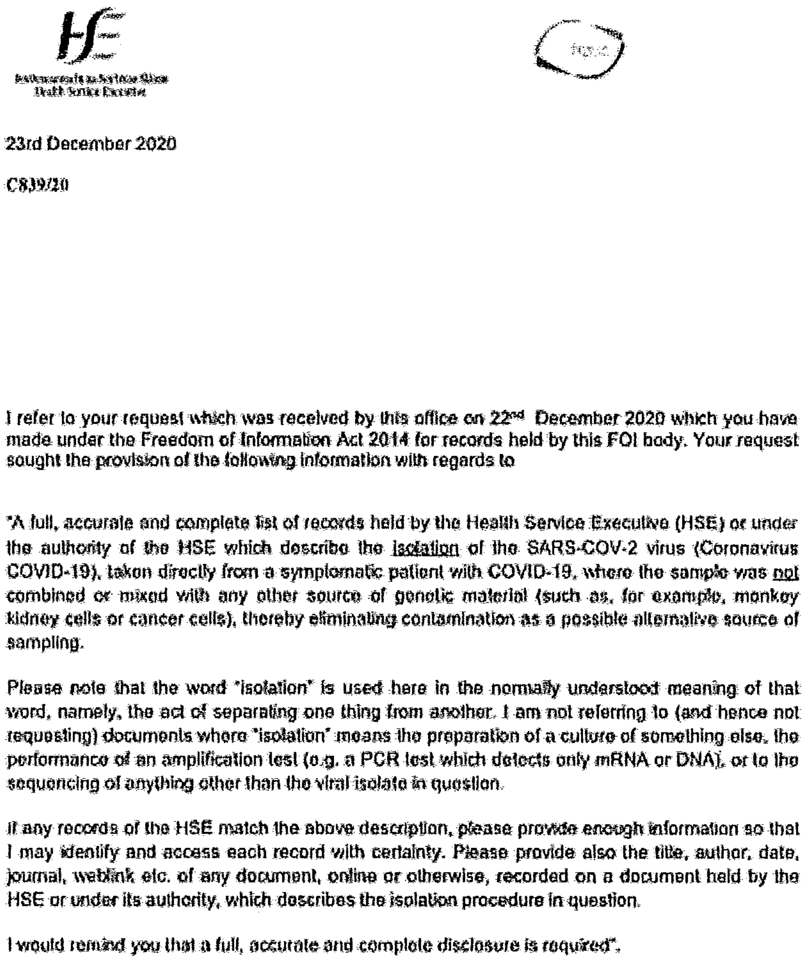
After months of painstaking freedom of information law requests the government of Ireland has finally come clean and admitted that it has no scientific proof that the SARS-CoV-2 virus (COVID-19) exists. Which other nations are going to be next and admit this pandemic was a scam?

"AS PART OF OUR LEGAL ACTION we had been demanding the evidence that this virus actually exists [as well as] evidence that lockdowns actually have any impact on the spread of viruses; that face-masks are safe, and do deter the spread of viruses – They don't. No such studies exist; that social distancing is based in science – It isn't. it's made up; that contact tracing has any bearing on the spread of a virus – of course it doesn't. This organisation here – is making it up as they go along." – Gemma O'Doherty

Originally streamed live from the office of Tony Holohan Chief Medical Officer of Ireland.

https://gemmaodoherty.com/

PSI Editor's Update 01.01.21: We Are Pleased To Announce We Now Have A PDF Copy Of The About Letter And Reproduce It Below For Reader Information:



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

23rd December 2020

C839/20

I refer to your request which was received by this office on 22nd December 2020 which you have made under the Freedom of Information Act 2014 for records held by this FOI body. Your request sought the provision of the following information with regards to

"A full, accurate and complete list of records held by the Health Service Executive (HSE) or under the authority of the HSE which describe the isolation of the SARS-COV-2 virus (Coronavirus COVID-19), taken directly from a symptomatic patient with COVID-19, where the sample was not combined or mixed with any other source of genetic material (such as, for example, monkey kidney cells or cancer cells), thereby eliminating contamination as a possible alternative source of sampling.

Please note that the word "isolation" is used here in the normally understood meaning of that word, namely, the act of separating one thing from another. I am not referring to (and hence not requesting) documents where "isolation" means the preparation of a culture of something else, the performance of an amplification test (e.g. a PCR test which detects only mRNA or DNA), or to the sequencing of anything other than the viral isolate in question.

If any records of the HSE match the above description, please provide enough information so that I may identify and access each record with certainty. Please provide also the title, author, date, journal, weblink etc. of any document, online or otherwise, recorded on a document held by the HSE or under its authority, which describes the isolation procedure in question.

I would remind you that a full, accurate and complete disclosure is required".

Following consultation with my colleagues, both from the scientific and medical areas of HPSC can confirm that we would hold no records in relation to your request. These are the reasonable steps I have taken to ascertain the whereabouts or existence of such records and unfortunately I must inform you that having undertaken these searches we were unable to locate the records in question. I am satisfied that all reasonable steps have taken to locate the records you have requested and must refuse therefore your request under Section 15.1(a) of the FOI Act 2014.

Rights of appeal

In the event that you are unhappy with this decision you may appeal this it. In the event that you need to make such an appeal, you can do so by writing to the HSE National Lead Office, FOI, DP and Record Management, Scott Building, Midland Regional Hospital Campus, Arden Road, Tullamore, Co. Offaly. Your correspondence should include a fee of €30 for processing the appeal. An internal review fee of €10 applies to medical card holders. Payment should be made by way of bank draft, money order, postal order or personal cheque made payable to the Health Service Executive. If you wish to make payment by electronic means please contact emma.kelly@hse.ie . You should make your appeal within 4 weeks from the date of this notification, where a day is defined as a working day excluding, the weekend and public holidays. However, the making of a late appeal may be permitted in appropriate circumstances. The appeal will involve a complete reconsideration of the matter by a more senior member of the staff of this body.

Should you have any questions or concerns regarding the above, please contact me by email on sinead.roche@hse.ie.

Yours sincerely,

Sinead Roche
FOI Decision Maker

APPENDIX [Note: highlighting in original from HSE]

Refusal on administrative grounds to grant FOI requests

15. (1) A head to whom an FOI request is made may refuse to grant the request where—
(a) the record concerned does not exist or cannot be found after all reasonable steps to ascertain its whereabouts have been taken,
(b) the FOI request does not comply with *section 12(1)(b)*,
(c) in the opinion of the head, granting the request would, by reason of the number or nature of the records concerned or the nature of the information concerned, require the retrieval and examination of such number of records or an examination of such kind of the records concerned as to cause a substantial and unreasonable interference with or disruption of work (including disruption of work in a particular functional area) of the FOI body concerned,
(d) the information is already in the public domain,
(e) publication of the record is required by law and is intended to be effected not later than 12 weeks after the receipt of the request by the head,
(f) the FOI body intends to publish the record and such publication is intended to be effected not later than 6 weeks after the receipt of the request by the head,
(g) the request is, in the opinion of the head, frivolous or vexatious or forms part of a pattern of manifestly unreasonable requests from the same requester or from

https://principia-scientific.com/irish-government-admits-covid-19-does-not-exist/

PUBLICIDAD

Medicina y salud

Los 4 postulados de Koch: qué son y qué explican

Un resumen de los postulados de Robert Koch, parte de la Historia de la Medicina.

Hubo un tiempo en el que no se sabía qué era lo que causaba las enfermedades. Había quienes pensaban que eran por designios celestiales, otros por miasmas, y otros por la posición de las estrellas.

Robert Koch, junto con otros científicos, descubrieron que muchas enfermedades tenían un origen infeccioso, es decir, eran causadas por agentes patógenos, como las bacterias.

En base a ello, propuso varios enunciados, llamados **postulados de Koch**, que han adquirido gran importancia en la historia de la microobiología y en el estudio de las enfermedades infecciosas. A continuación veremos el por qué, y qué dicen exactamente estos postulados.

- Artículo relacionado: "**Psicología de la Salud: historia, definición y ámbitos de aplicación**"

¿Qué son los postulados de Koch?

Los postulados de Koch son cuatro **criterios que fueron diseñados para establecer la relación causal entre agentes patógenos, mayormente microbios, y las enfermedades**. Fueron formulados en 1884 por el médico alemán Robert Koch, en colaboración con Friedrich Loeffler, basándose en conceptos descritos anteriormente por Jakob Henle. Es por este motivo que también son conocidos como modelo de

Koch-Henle. Los postulados fueron presentados en 1890 en el Congreso Internacional de Medicina en Berlín por primera vez.

Estos postulados **han sido un gran hito en la historia de la medicina, y han contribuido a que asomara la cabeza la microbiología**. Además, supuso un antes y después en la historia de las ciencias médicas, dado que la propuesta de Koch ha sido considerada una auténtica revolución bacteriológica, permitiendo entender cómo la relación entre agentes patógenos y las enfermedades. Antes de este modelo, muchas personas, médicos y científicos incluidos, creían que las enfermedades podían ser causadas por los designios celestiales, miasmas o por la astrología.

Pese a todo esto, con el paso del tiempo acabaron siendo revisados, proponiéndose actualizaciones más adaptadas al conocimiento científico del siglo siguiente. Además, **la concepción original de esto cuatro postulados tenía ciertos puntos débiles**, lo cual hizo que, incluso el propio Koch fuera consciente de que se tendría que ahondar más en el estudio de las enfermedades infecciosas.

- Quizás te interese: "**Las diferencias entre síndrome, trastorno y enfermedad**"

¿Cuáles son?

Los postulados de Koch originales fueron tres cuando se presentaron por primera vez en el Décimo Congreso Internacional de Medicina en Berlín. El cuarto fue añadido en posteriores revisiones:

1. Primer postulado

"El microorganismo debe poder ser encontrado en abundancia en todos los organismos que estén padeciendo la enfermedad, pero no debería encontrarse en los que estén sanos".

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Esto quiere decir que si se sospecha que un microbio es el agente causal de una enfermedad en particular, **debería poderse encontrar en todos los organismos que estén sufriendo dicha enfermedad, mientras que los individuos sanos no deberían tenerlo.**

Pese a que este postulado es fundamental dentro de la concepción bacteriológica de Koch, él mismo abandonó esta concepción universalista cuando vio casos que rompían esta regla: los portadores asintomáticos.

Las personas asintomáticas o que tienen síntomas muy leves son un fenómeno muy común en varias enfermedades infecciosas. Incluso el propio Koch observó que esto ocurría en enfermedades como el cólera o la fiebre tifoidea. También se da en enfermedades de origen vírico, como la polio, el herpes simple, el virus de la inmunodeficiencia humana (VIH) y la hepatitis C.

- Quizás te interese: "**Los 5 tipos de virus, y cómo funcionan**"

2. Segundo postulado

“El microorganismo debe poder ser extraído y aislado de un organismo enfermo y cultivarse en un cultivo puro”.

La aplicación experimental de los postulados de Koch empieza con este segundo enunciado, el cual viene a decir que si se tiene la sospecha de que un microbio causa una enfermedad, este **debería poder ser aislado del individuo infectado y cultivarse por separado**, por ejemplo, en un cultivo in vitro con condiciones controladas.

Este postulado también viene a estipular que el microorganismo patógeno no se da en otros contextos infecciosos, ni tampoco de forma fortuita. Es decir, no es aislado de pacientes que presentan otras enfermedades, en los cuales se puede encontrar como un parásito no patogénico.

Sin embargo, **este postulado falla con respecto a los virus**, los cuales, dado que son parásitos obligados, y teniendo en cuenta las técnicas de finales del siglo XIX, no era posible extraerlos para cultivarlos en condiciones controladas. Necesitan células en las que hospedarse.

3. Tercer postulado

"El microorganismo que se ha cultivado en un cultivo debería poder causar la enfermedad una vez introducido en un organismo sano".

Es decir, de acuerdo con el modelo Koch-Henle, si una bacteria ha sido cultivada en un cultivo y se presenta en la cantidad y estadio de maduración apropiado como para causar una patología, **al ser inoculada en un individuo sano debería causarle la enfermedad**.

Al introducirlo en un individuo sano se deberían observar, con el paso del tiempo, los mismos síntomas que se presentan en los individuos enfermos de los que se extrajo el patógeno.

Este postulado, sin embargo, está formulado de forma en el que ese "debería" no es sinónimo de "siempre tendría que ser". El propio Koch observó que **en enfermedades como la tuberculosis o la cólera, no todos los organismos que eran expuestos al agente patógeno iban a causar la infección**.

Hoy se sabe que el hecho de que un individuo con el patógeno no muestre la enfermedad puede ser debido a factores del individuo, tales como el tener una buena salud física, un sistema inmune sano, haber estado expuesto al agente previamente y haber desarrollado inmunidad ante él o, simplemente, haber sido vacunado.

4. Cuarto postulado

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"El mismo patógeno debería poder ser re-aislado de individuos a quienes se les inoculó experimentalmente, y ser idéntico al patógeno extraído del primer individuo enfermo al que se le extrajo".

Este último postulado **fue añadido posteriormente al Congreso de Medicina de Berlín en el que Koch presentó los tres postulados anteriores**. Fue añadido por otros investigadores, quienes lo consideraron relevante, y estipula, básicamente, que el patógeno que ha causado la enfermedad en otros individuos debería ser el mismo que ha causado en los primeros casos.

Revisión de Evans

Casi un siglo después, en 1976, **Sir David Gwynne Evans incorporó a estos principios algunas ideas actualizadas sobre epidemiología e inmunología**, especialmente sobre la respuesta inmunológica de los hospedadores disparadas ante la presencia de un microorganismo infeccioso.

Los postulados de Evans son los siguientes:

- La proporción de individuos enfermos debería ser mayor entre quienes han sido expuestos a la supuesta causa, en comparación con quienes no lo están.
- La exposición a la supuesta causa o agente patógeno debería ser más frecuente entre aquellos individuos quienes padecen la enfermedad que en aquellos quienes no la padecen.
- El número de casos nuevos de la patología debería ser destacablemente mayor en individuos expuestos al supuesto patógeno en comparación a los no expuestos.
- Con el paso del tiempo, la enfermedad debería seguir, tras la exposición al agente causal, un periodo de distribución e incubación, que debería poder representarse en un gráfico en forma de campana.

- Tras haber sido expuesto, el hospedador debería presentar un amplio abanico de respuestas, yendo desde leves hasta graves, a lo largo de un gradiente biológico lógico.
- Mediante prevención o intervención en el huésped, debe disminuir o eliminarse los síntomas de la enfermedad.
- La reproducción experimental de la enfermedad debería tener mayor frecuencia en organismos expuestos a su supuesta causa, en comparación con quienes no han sido expuestos. Esta exposición puede ser deliberada en voluntarios, inducida experimentalmente en el laboratorio o demostrada mediante la modificación controlada de la exposición natural.
- La eliminación o modificación de la supuesta causa patógena debería reducir la frecuencia de presentación de la enfermedad.
- La prevención o modificación de la respuesta del organismo hospedador debería reducir o eliminar la enfermedad producida tras la exposición al agente.
- Todas las relaciones y asociaciones del patógeno con la enfermedad deberían ser biológica y epidemiológicamente verosímiles.

Limitaciones del modelo Koch-Henle

Hay que entender que **los postulados, pese a que supusieron un importante hito que acentuó la revolución bacteriológica, se concibieron en el siglo XIX**. Teniendo en cuenta que la ciencia suele avanzar a pasos agigantados, no es de extrañar que los postulados de Koch tengan sus limitaciones, algunas de ellas ya observadas en su tiempo.

Con el descubrimiento de los virus, que son agentes patógenos acelulares y parásitos obligados, junto con bacterias que no se acoplaban al modelo de Koch-Henle, los postulados han tenido que ser revisados, siendo un ejemplo de ello la propuesta de

Evans. Los postulados de Koch **son considerados fundamentalmente obsoletos desde los años 50 del siglo pasado, aunque no cabe duda que poseen una gran importancia histórica**.

Otra limitación es la existencia de patógenos que causan enfermedades diferentes de individuo en individuo y, también, enfermedades que se dan con la presencia de dos patógenos distintos, o incluso individuos que tienen el patógeno pero nunca manifestarán la enfermedad. Es decir, pareciera que la relación causal patógeno-enfermedad es mucho más compleja que lo que el modelo propuso en un principio, que concebía esta relación causal de forma mucho más lineal a cómo hoy en día se sabe que se producen las enfermedades y su relación con agentes patógenos.

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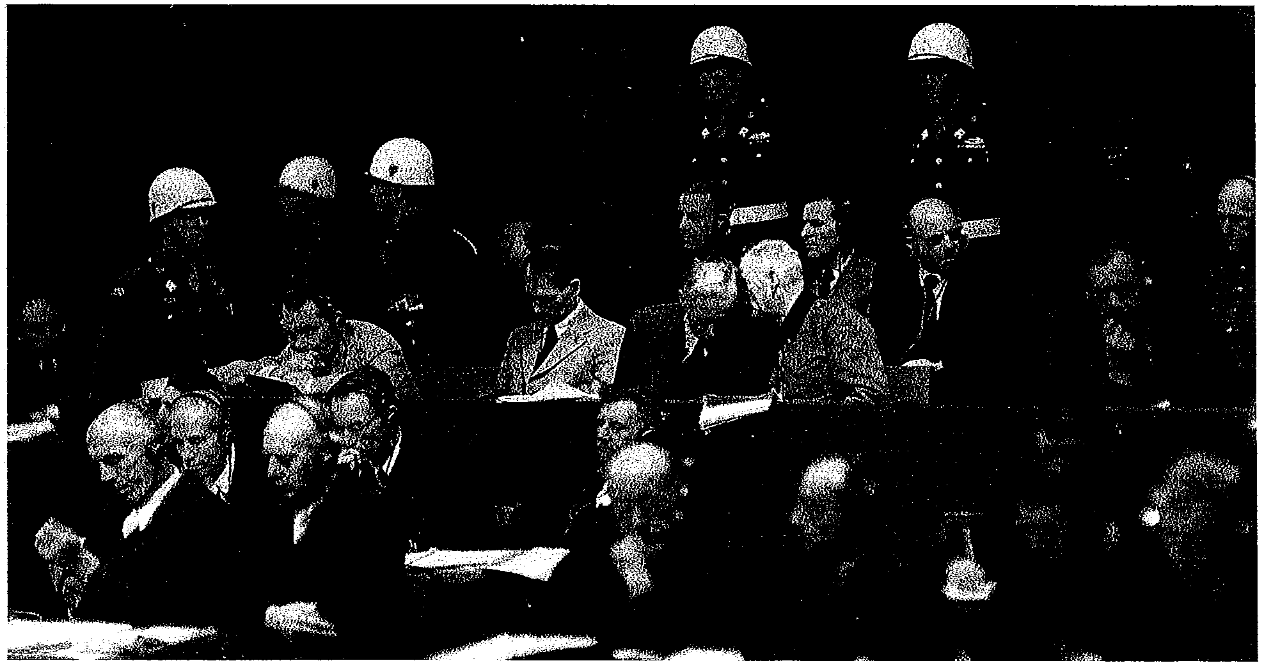


El mayor Nuremberg de todos los tiempos se prepara

18 de febrero de 2021

Por Jean-Michel Grau (traducción del francés):

Publicidad

Ayer se preparó un segundo tribunal de Nuremberg, con la creación de una «acción colectiva» bajo la égida de miles de abogados de todo el mundo que respaldan al abogado estadounidense-alemán Reiner Fuellmich, el cual está procesando a los responsables del escándalo del Covid-19 manipulado por el Foro de Davos. A este respecto, cabe recordar que Reiner Fuellmich es el abogado que logró condenar al gigante automovilístico Volkswagen en el caso de los catalizadores manipulados. Y es el mismo abogado que consiguió condenar al Deutsche Bank como empresa criminal.

Según Reiner Fuellmich, todos los fraudes cometidos por las empresas alemanas son irrisorios en comparación con los daños que ha causado y sigue causando la crisis del Covid-19. Esta crisis debería rebautizarse como el «Escándalo del Covid-19» y todos los responsables deberían ser procesados por daños civiles debido a la manipulación y falsificación de los protocolos de ensayo. Por lo tanto, una red internacional de abogados de negocios alegará el **mayor caso de agravio de**

todos los tiempos, el escándalo de fraude Covid-19, que mientras tanto se ha convertido en el mayor crimen contra la humanidad jamás cometido. Por iniciativa de un grupo de abogados alemanes se ha creado una comisión de investigación Covid-19 con el objetivo de interponer una demanda colectiva internacional utilizando el derecho anglosajón.

Esta es la traducción resumida de la última comunicación del Dr. Fuellmich del 15/02/2021

«Las audiencias de un centenar de científicos, médicos, economistas y abogados de renombre internacional que ha llevado a cabo la Comisión de Investigación de Berlín sobre el asunto Covid-19 desde el 10/07/2020 han demostrado entretanto con una probabilidad cercana a la certeza que el escándalo del Covid-19 no fue en ningún momento un problema de salud. Se trataba más bien de concretar el poder -ilegítimo, porque fue obtenido por métodos criminales- de la corrupta «camarilla de Davos», transfiriendo la riqueza del pueblo a los miembros de la camarilla de Davos, destruyendo, entre otras cosas, las pequeñas y medianas empresas en particular. Plataformas como Amazon, Google, Uber, etc. podrían así apropiarse de su cuota de mercado y riqueza».

Publicidad

Estado de la investigación del Comité Covid-19

A. Covid-19 como táctica de distracción por parte de las «élites» corporativas y políticas para desplazar la cuota de mercado y la riqueza de las pequeñas y medianas empresas a plataformas globales como Amazon, Google, Uber, etc.

B. Contribución del Impuesto Audiovisual a la reconstrucción de un nuevo panorama mediático que ofrezca una información verdaderamente independiente

C. Asegurar las estructuras agrícolas regionales

D. Asegurar una moneda regional para evitar que una nueva moneda venga «de arriba» para ser asignada en caso de buena conducta

E. Consideraciones psicológicas de la situación: ¿Cómo se produjo?

Acciones de anulación de la aprobación de una vacuna, presentadas contra la Comisión Europea, juicio en Nueva York sobre la situación de las pruebas PCR, juicios en Alemania, juicios en Canadá, juicios en Australia, juicios en Austria, juicios en el Tribunal Internacional de Justicia y en el Tribunal Europeo de Derechos Humanos.

«Hemos visto lo que se ha confirmado una y otra vez: la peligrosidad del virus es prácticamente la misma que la de la gripe estacional, independientemente de que se trate de un nuevo virus (total o parcialmente fabricado) o de que simplemente estemos ante una gripe rebautizada como «pandemia Covid-19». Mientras tanto, las pruebas PCR de Drosten no pueden decirnos nada sobre las infecciones contagiosas. Por si fuera poco, los daños sanitarios y económicos causados por las medidas anticovícolas han sido tan devastadores que hay que hablar de un nivel de destrucción históricamente único.

«El hecho de que la salud nunca ha estado en cuestión es particularmente obvio, excepto que las inyecciones de sustancias genéticamente experimentales disfrazadas de «vacunas» están causando ahora graves daños, incluso consecuencias fatales, a escala masiva. La población mundial ha sido utilizada como conejillo de indias para estas inyecciones genéticas experimentales de forma progresiva y extremadamente rápida. Para sumir a la población en el pánico, se han introducido medidas de contención peligrosas y nocivas (incluso según la OMS) de uso obligatorio, innecesario y peligroso de mascarillas y de distanciamiento social, innecesario y contraproducente. La población estaba así «preparada» para las inyecciones.

Publicidad

«Mientras tanto, cada vez más personas, y no sólo abogados -y con razón-, exigen, además del fin inmediato de estas medidas asesinas, una revisión judicial por parte de un tribunal internacional verdaderamente independiente según el modelo de los juicios de Nuremberg. En el siguiente enlace se puede encontrar un ejemplo de dicha demanda y un emotivo extracto de un discurso del médico inglés Dr. Vernon Coleman: .

Además, una entrevista con un denunciante de una residencia de ancianos de Berlín atestigua que de 31 personas vacunadas allí, algunas de ellas a la fuerza, en presencia de soldados de la Bundeswehr, y que dieron negativo antes de la vacunación, 8 han muerto ahora y 11 sufren graves efectos secundarios». 1

Reunión extraordinaria del Comité Covid de Berlín Miércoles 17/02/2021

«En este contexto, el miércoles 17/02/2021 tendrá lugar una reunión extraordinaria del Comité Covid de Berlín, en directo y con la participación de numerosos invitados a través de Zoom.

Publicidad

A partir de las 14.00 horas, se resumirá el estado de la situación. Además, se debatirá cómo se pueden retener las contribuciones del impuesto sobre el canon audiovisual y utilizarlas para la reconstrucción de un nuevo panorama mediático que sirva realmente a la libertad de expresión, y cómo se pueden recuperar las contribuciones ya pagadas por la propaganda insensata de los últimos 11 meses mediante una notificación de impago.

Habrá contribuciones y debates sobre cómo se puede asegurar el suministro de alimentos, en particular mediante el fortalecimiento de la agricultura regional; pero también mediante la creación de monedas regionales, si es necesario con el regreso de la UE a la CEE, sobre cómo garantizar que la política de la «camarilla de Davos», basada en la impresión de dinero de la nada, pueda ser detenida y se logre un retorno a las monedas estables.

Sobre todo, los expertos nos explicarán cómo ha podido ocurrir que nos encontremos en esta situación de chantaje inimaginable incluso hace un año.

En la segunda parte de la sesión, que comenzará a las 19.00 horas, personalidades de alto nivel y de renombre mundial comentarán el estado de los litigios internacionales actuales, incluidas las diversas acciones colectivas, como se ha resumido anteriormente. Pero también se debatirá cómo los principales responsables, en particular los políticos, de los crímenes contra la humanidad aquí cometidos pueden y deben responder ante el derecho civil y penal en el marco de un nuevo Tribunal Internacional de Justicia que se creará de acuerdo con las directrices de los juicios de Nuremberg con distribución internacional».

Publicidad.

Comentarios:
Para entender lo que está en juego con este nuevo tribunal de Nuremberg para juzgar el mayor caso de agravio de todos los tiempos, es necesario tirar del hilo de la mentira del Dr. Drosten sobre la falsificación del protocolo de pruebas PCR en nombre de la camarilla de Davos a lo que todo se va a reducir: los patrocinadores de la oligarquía financiera, Klaus Schwab, el gran artífice de esta gigantesca crisis de rehenes, los políticos al frente de la UE, el brazo armado de la aplicación de las directivas de la Drosten y de la OMS que llevaron ayer a todos los gobiernos occidentales a tomar las devastadoras decisiones de contención, toques de queda, máscaras obligatorias y distanciamiento social, y hoy de vacunas letales para los más mayores.
«Son estas verdades las que harán caer las máscaras de los responsables de los crímenes cometidos. Para los políticos que han confiado en estas cifras corruptas», dice el Dr. Fuellmich, «los hechos que aquí se presentan son el salvavidas que les ayudará a poner las cosas en su sitio y a iniciar el tan necesario debate científico para evitar hundirse con estos charlatanes criminales».

En segundo lugar, a la luz de esta última comunicación del Dr. Fuellmich, son de especial interés dos propuestas de la reunión extraordinaria del Comité Covid en Berlín:

En primer lugar, la forma de asegurar el suministro de alimentos, que parece algo surrealista a la luz de la situación actual. Si se observa la agenda de Klaus Schwab para el Foro de Davos, no es así. De hecho, ha pronosticado una ruptura de la cadena alimentaria ya a finales del segundo semestre de 2021.

A continuación, la creación de monedas regionales. Aquí está claro que el Comité Covid de Berlín ya está anticipando el próximo crack bursátil mundial, que la oligarquía financiera del Foro de Davos pretende aprovechar para crear la moneda digital europea en espera de una moneda mundial para crear un crédito social al estilo chino del que dependerá la clase media de todos los pueblos arruinados por el cierre de sus empresas, PYMES, industrias culturales y turísticas, instalaciones deportivas, etc.

Estos dos aspectos por sí solos de la toma de rehenes 2.0 de la que el mundo occidental es víctima desde hace casi un año deberían ser, lógicamente, suficiente motivación para hacernos comprender definitivamente que estamos ante un «populicidio» que sólo pide aplastarnos si permanecemos inertes, con los brazos colgando sin hacer nada.

Por eso es importante que todos hagamos ahora todo lo posible para que esta coalición jurídica internacional pueda ser operativa lo antes posible. Para ello, todos aquellos que deseen sumarse a la acción colectiva de los abogados franceses para participar en esta reconquista de nuestras libertades deben ponerse en contacto ya antes del 21 de febrero con la Acción Colectiva 4. Nuestra supervivencia tiene este precio, así como el futuro de nuestros hijos.

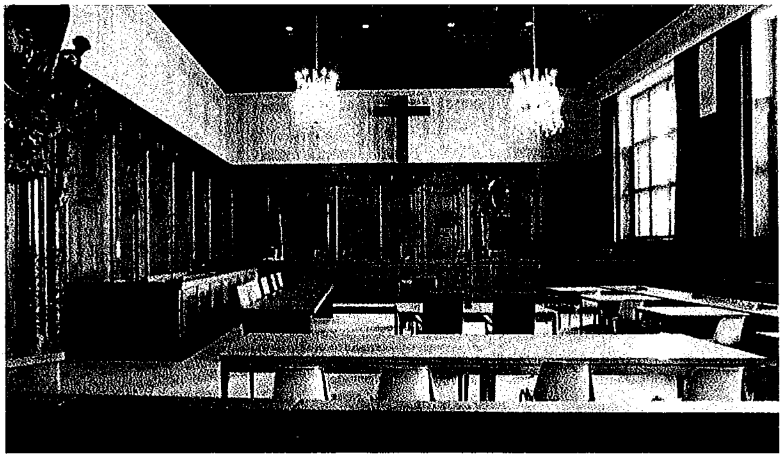
https://trikooba.com/2021/02/18/el-mayor-nuremberg-de-todos-los-tiempos-se-prepara/

Evolve to Ecology

Ecosolutionaries-Be a Part of the Solution, Not the Crisis

Dr Reiner Fuellmich begins Legal Litigation on the Covid-19 Fraud- The Greatest Crime Against Humanity

Evolve to EcologyFebruary 27, 20212021, 5G, Autism, bat CoV, Bill Gates, biological warfare, BioNtech, BNT162b, Brainwashing, capitalism, Central Bank, china, CO2, Compassion, Consciousness, Consciousness, Coronavirus, Corpocracy, Corporatization, corruption, COVID 19 Vaccine, COVID-19, Cyberwarfare, Dan Klaus Schwab, depression, disposable masks, DNA, Dr Fauci, Dr Wodarg, Dr. Garth Nicolson, Dr. Yeadon, Earth, ecological illiteracy, Education, Election 2020, Empathy, Environmental Conservation, Environmental Education, environmental law, environmental waste, Exploitation, free speech, Freedom, Gaia, Geopolitics, Google, greed, grief, H1N1, Happiness, Health, Hope, Human Rights, immune reaction, Imperialism, Inflammation, Ivermectin, Law, Mind Control, mRNA, Mycoplasma, Oxygen, PCR test, Pfizer, Pharmaceutical, Plutocracy, Political, politics, pollution, polyethylene glycol, polypropolene, Prism, Privacy, Psychology, Reiner Fuellmich, Robert F. Kennedy Jr, Rule of Law, Science, Simon Dolan, suicide, surveillance, Technocracy, Terrorism, Tracking and Tracing, transhumanism, Ultra Vires, vaccine damage, Vaccine Injury, Vaccine Safety, Vaccine Technology



According to American-German lawyer Dr. Reiner Fuellmich, all cases of fraud in German companies are meagre in comparison to the level and depth of damage that has been caused and continues to be caused to humanity by the Covid-19 regulations and this orchestrated crisis. A German Corona Investigative Committee has been working tirelessly since July 10, 2020 to answer some important questions, this Committee has been listening to a large number of international scientists' and experts' testimony to find answers to questions about the corona crisis, which more and more people worldwide are asking.

This Covid-19 crisis should be renamed the "Covid-19 scandal" and all those responsible, such as the Davos Forum who have manipulated much of the information, should be prosecuted for civil damages caused by tampering and falsified test protocols. For this reason, an international network of corporate lawyers and scientists are negotiating the greatest case of all time, the Covid-19 fraud scandal, which has now become the greatest crime against humanity of all time, is also being called the world's second Nuremberg tribunal.

Under the initiative of a group of German lawyers, a commission of inquiry into Covid-19 was opened to initiate an international class action lawsuit under Anglo-Saxon law. Dr Reiner Fuellmich is the lawyer who has managed to convict the car giant Volkswagen for the modified catalytic converters. This same attorney successfully convicted Deutsche Bank as a criminal enterprise, the bank agreed to pay more than $ 130 million in damages, as a consequence.

Crimes against humanity were first defined in connection with the Nuremberg trials after World War II, that is, when they dealt with the main war criminals of the Third Reich. Crimes against humanity are today regulated in section 7 of the International Criminal Code. The three major questions to be answered in the context of a judicial approach to the corona scandal are:

1. Is there a corona pandemic or is there only a PCR-test pandemic? Specifically, does a positive PCR-test result mean that the person tested is infected with Covid-19, or does it mean absolutely nothing in connection with the Covid-19 infection?

2. Do the so-called anti-corona measures, such as the lockdown, mandatory face masks, social distancing, and quarantine regulations, serve to protect the world's population from corona, or do these measures serve only to make people panic so that they believe – without asking any questions – that their lives are in danger, so that in the end the pharmaceutical and tech industries can generate huge profits from the sale of PCR tests, antigen and antibody tests and vaccines, as well as the harvesting of our genetic fingerprints?

3. Is it true that the German government was massively lobbied, more so than any other country, by the chief protagonists of this so-called corona pandemic, Mr. Drosten, virologist at charity hospital in Berlin; Mr. Wieler, veterinarian and head of the German equivalent of the CDC, the RKI; and Mr. Tedros, Head of the World Health Organization or WHO; because Germany is known as a particularly disciplined country and was therefore to become a role model for the rest of the world for its strict and, of course, successful adherence to the corona measures?

Answers to these three questions are urgently needed because the allegedly new and highly dangerous coronavirus has not caused any excess mortality anywhere in the world, and certainly not in Germany. But the anti-corona measures, whose only basis are the PCR-test results, which are in turn all based on the German Drosten test, have, in the meantime, caused the loss of innumerable human lives and have destroyed the economic existence of countless companies and individuals worldwide. In Australia, for example, people are thrown into prison if they do not wear a mask or do not wear it properly, as deemed by the authorities. In the Philippines, people who do not wear a mask or do not wear it properly, in this sense, are getting shot in the head.

The PCR Test Fraud and COVID-19 will be the Case of the Century

Dr. Reiner Fuellmich has taken on a grand responsibility which he is driven to carry for the misjustices carried daily as a consequence of the PCR Test Fraud and COVID-19 government and media fraud, that humanity has been subjected to. Fuellmich is not alone, he is supported by the work of an international team of court judges, doctors, scientists, economists, entrepreneurs, experts and business lawyers who will plead the biggest tort case of all time, the Covid-19 fraud scandal is the biggest fraud of the century.

According to the Corona Committee the assertion that the lockdown was necessary because there were so many different infections with SARS-COV-2, and because the healthcare systems would be overwhelmed is wrong for several reasons, and from other data that has become available in the meantime:

A. The lockdown was imposed when the virus was already retreating. By the time the lockdown was imposed, the alleged infection rates were already dropping again.

B. There's already protection from the virus because of cross- or T-cell immunity. Apart from the above mentioned lockdown being imposed when the infection rates were already dropping, there is also cross- or T-cell immunity in the general population against the corona viruses contained in every flu or influenza wave. This is true, even if this time around, a slightly different strain of the coronavirus was at work. And that is because the body's own immune system remembers every virus it has ever battled in the past, and from this experience, it also recognizes a supposedly new, but still similar, strain of the virus from the corona family. Incidentally, that's how the PCR test for the detection of an infection was invented by now infamous Professor Drosten.

At the beginning of January of 2020, based on this very basic knowledge, Mr. Drosten developed his PCR test, which supposedly detects an infection with SARS-COV-2, without ever having seen the real Wuhan virus from China, only having learned from social media reports that there was something going on in Wuhan, he started tinkering on his computer with what would become his corona PCR test. For this, he used an old SARS virus, hoping it would be sufficiently similar to the allegedly new strain of the coronavirus found in Wuhan. Then, he sent the result of his computer tinkering to China to determine whether the victims of the alleged new coronavirus tested positive. They did. And that was enough for the World Health Organization to sound the pandemic alarm and to recommend the worldwide use of the Drosten PCR test for the detection of infections with the virus now called SARS-COV-2.

C. And this is the most important part of our fact-finding: the PCR test is being used on the basis of false statements, NOT based on scientific facts with respect to infections. In the meantime, we have learned that these PCR tests, contrary to the assertions of Messrs. Drosten, Wieler and the WHO, do NOT give any indication of an infection with any virus, let alone an infection with SARS-COV-2. Not only are PCR tests expressly not approved for diagnostic purposes, as is correctly noted on leaflets coming with these tests, and as the inventor of the PCR test, Kary Mullis, who died in 2019, has repeatedly emphasized. Instead, they're simply incapable of diagnosing any disease.'

"That is: contrary to the assertions of Drosten, Wieler and the WHO, which they have been making since the proclamation of the pandemic, a positive PCR-test result does not mean that an infection is present. If someone tests positive, it does NOT mean that they're infected with anything, let alone with the contagious SARS-COV-2 virus. Even the United States CDC, even this institution agrees with this, and I quote directly from page 38 of one of its publications on the coronavirus and the PCR tests, dated July 13, 2020. First bullet point says:

"Detection of viral RNA may not indicate the presence of infectious virus or that 2019 nCOV [novel coronavirus] is the causative agent for clinical symptoms."

Second bullet point says:
"The performance of this test has not been established for monitoring treatment of 2019 nCOV infection." Third bullet point says: "This test cannot rule out diseases caused by other bacterial or viral pathogens."

"It is still not clear whether there has ever been a scientifically correct isolation of the Wuhan virus, so that nobody knows exactly what we're looking for when we test, especially since this virus, just like the flu viruses, mutates quickly. The PCR swabs take one or two sequences of a molecule that are invisible to the human eye and therefore need to be amplified in many cycles to make it visible.

Everything over 35 cycles is – as reported by the New York Times and others – considered completely unreliable and scientifically unjustifiable. However, the Drosten test, as well as the WHO-recommended tests that followed his example, are set to 45 cycles. Can that be because of the desire to produce as many positive results as possible and thereby provide the basis for the false assumption that a large number of infections have been detected?'

The test cannot distinguish inactive and reproductive matter. That means that a positive result may happen because the test detects, for example, a piece of debris, a fragment of a molecule, which may signal nothing else than that the immune system of the person tested won a battle with a common cold in the past.'

Meanwhile, a number of highly respected scientists worldwide assume that there has never been a corona pandemic, but only a PCR-test pandemic. This is the conclusion reached by many German scientists, such as professors Bhakti, Reiss, Mölling, Hockertz, Walach and many others, including the above-mentioned Professor John Ioannidis, and the Nobel laureate, Professor Michael Levitt from Stanford University.'

The most recent such opinion is that of the aforementioned Dr. Mike Yeadon, a former Vice-President and Chief Science Officer at Pfizer, who held this position for 16 years. He and his co-authors, all well-known scientists, published a scientific paper in September of 2020 and he wrote a corresponding magazine article on September 20, 2020. Among other things, he and they state – and I quote: "We're basing our government policy, our economic policy, and the policy of restricting fundamental rights, presumably on completely wrong data and assumptions about the coronavirus. If it weren't for the test results that are constantly reported in the media, the pandemic would be over because nothing really happened. Of course, there are some serious individual cases of illness, but there are also some in every flu epidemic. There was a real wave of disease in March and April, but since then, everything has gone back to normal. Only the positive results rise and sink wildly again and again, depending on how many tests are carried out. But the real cases of illnesses are over. There can be no talk of a second wave. The allegedly new strain of the coronavirus is ..."

– Dr. Yeadon continues –

"... only new in that it is a new type of the long-known corona virus. There are at least four coronaviruses that are endemic and cause some of the common colds we experience, especially in winter. They all have a striking sequence similarity to the coronavirus, and because the human immune system recognizes the similarity to the virus that has now allegedly been newly discovered, a T-cell immunity has long existed in this respect. 30 per cent of the population had this before the allegedly new virus even appeared. Therefore, it is sufficient for the so-called herd immunity that 15 to 25 per cent of the population are infected with the allegedly new coronavirus to stop the further spread of the virus. And this has long been the case."
Regarding the all-important PCR tests, Yeadon writes, in a piece called "Lies, Damned Lies and Health Statistics: The Deadly Danger of False Positives", dated September 20, 2020, and I quote "The likelihood of an apparently positive case being a false positive is between 89 to 94 per cent, or near certainty."

Dr. Yeadon, in agreement with the professors of immunology Kamera from Germany, Kappel from the Netherlands, and Cahill from Ireland, as well as the microbiologist Dr. Arve from Austria, all of whom testified before the German Corona Committee, explicitly points out that a positive test does not mean that an intact virus has been found.
– Dr. Fuellmich's Testimony

While we have established that the PCR tests are scientifically flawed and can't tell us about contagious infections, they were not designed for this purpose. Hence so many false positives, they have been used as a tool by health advisors and government regulators and their media echo chamber, to instil fear and manipulate people to give up their freedoms and even to coerce people into taking an experimental biological covid-19 "vaccine". To make matters worse, the health and economic damage caused by the governments regulations for covid-19 is so devastating, that it is necessary to speak of a historically unique level of destruction on society, on people, psychologically, on our humanity, physically, economically, and more socially.

COVID-19 is not a Health Issue, its a Power Transition....

According to Fuellmich, Covid-19 scandal has never been a health issue. Dr. Fuellmich on February 15, 2020:

"The hearings of hundreds of scientists, doctors, economists and lawyers of international renown, among others, conducted by the Berlin Commission of Inquiry into the Covid-19 affair since October 7, 2020, have now shown with a probability approaching 100% certainty that the Covid -19 scandal was never a health issue. "

"Rather, it was a matter of strengthening power, illegally obtained by criminal methods of the corrupt Davos cabal, by transferring the wealth of the population to the members of Davos over the backs of the small, among others. and especially medium-sized companies. "

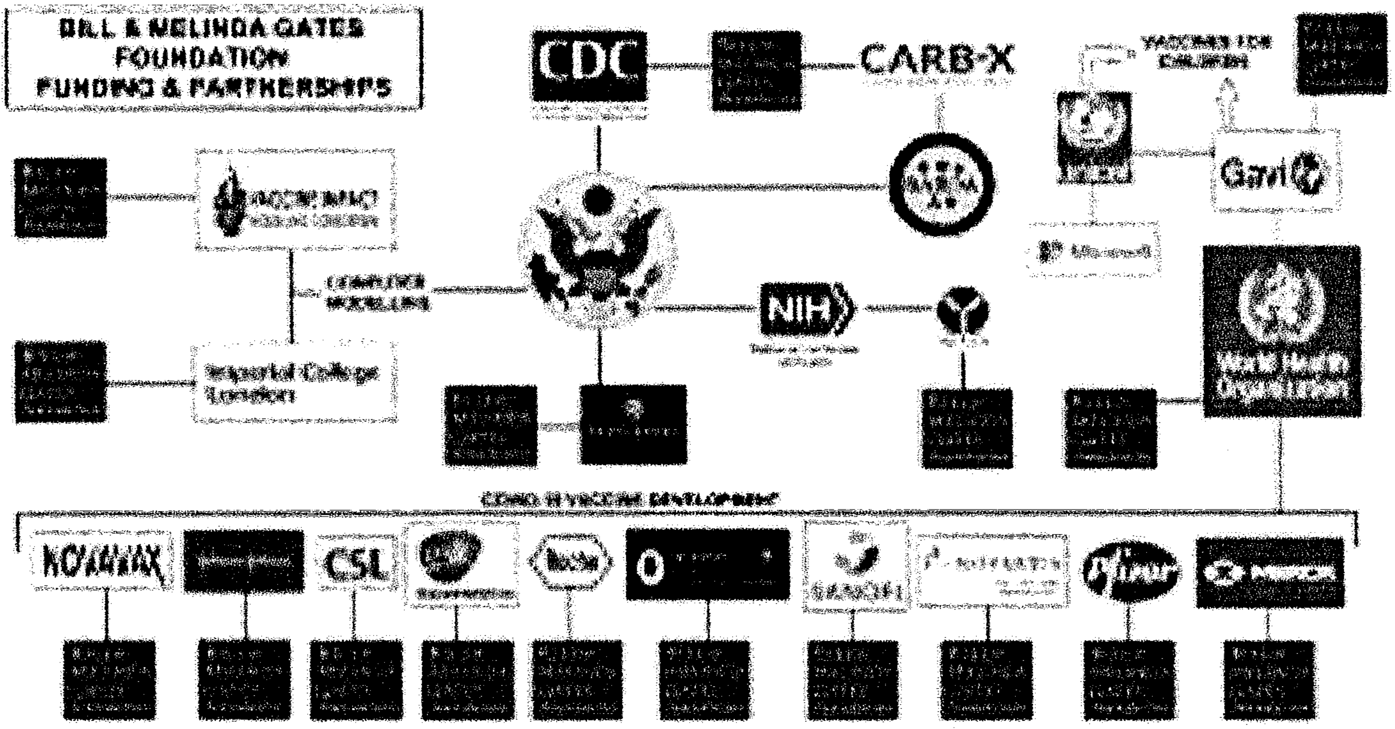
Then, the so-called "Panic Paper" was leaked, which was written by the German Department of the Interior. Its classified content shows beyond a shadow of a doubt that, in fact, the population was deliberately driven to panic by politicians and mainstream media. The accompanying irresponsible statements of the Head of the RKI – remember the German equivalent of the CDC – Mr. Wieler, who repeatedly and excitedly announced that the corona measures must be followed unconditionally by the population without them asking any question, shows that that he followed the script verbatim. In his public statements, he kept announcing that the situation was very grave and threatening, although the figures compiled by his own Institute proved the exact opposite. Among other things, the "Panic Paper" calls for children to be made to feel responsible – and I quote – "for the painful tortured death of their parents and grandparents if they do not follow the corona rules"

The committee's conclusion is that Covid-19 is being used as a diversionary tactic by corporate and political 'elites' with the aim of shifting market shares and wealth from small and medium-sized businesses to global platforms such as Amazon, Google, Uber, and other big-tech and multinational companies. "Platforms like Amazon, Google, Uber and other big tech have mastered their market shares and their wealth,"- said Dr Fuellmich.

Countless appeals for annulment of vaccination approval have been filed against the European Commission, lawsuits in New York over the statute of PCR tests, German lawsuits, Canadian lawsuits, Australian lawsuits, Austrian lawsuits and lawsuits in the International Court of Justice and in the European court for human rights.

"We have seen what has been confirmed time and time again: the virus's danger is about the same as that of the seasonal flu, regardless of whether it is a new virus or whether we are simply dealing with an influenza dubbed the Covid-19 pandemic"

The manipulation of information has coerced and instilled panic in global populations, causing dangerous and damaging containment measures, (especially by the WHO) with these mandatory mask wearing regulations that are damaging to children and adults health for long term use, in addition to social distancing and social isolation with lockdowns, which has been psychologically damaging and continues to be useless and counterproductive. The population was thus manipulated to be "ready" for these experimental biological agents, these injections, that the governments are calling vaccines.


BILL & MELINDA GATES FOUNDATION FUNDING & PARTNERSHIPS
CDC
CARB-X
VACCINES FOR CHILDREN
Gavi
COMPUTER MODELLING
Imperial College London
NIH
World Health Organization
COVID-19 VACCINE DEVELOPMENT
NOVAVAX
CSL
SANOFI
Pfizer

The world's population serves as guinea pigs for these experimental genetically modifying injections that we do not know the long-term consequences of, and which do not protect people from a constantly mutating and changing virus. Meanwhile, more and more people, not just lawyers, are demanding a judicial review by a truly independent international tribunal, along the lines of the original Nuremberg trials, with the aim to the immediate end of these deadly measures.

An example of such a request from the English doctor Dr Vernon Coleman was found on YouTube but has been removed:

Moreover, an interview with a whistleblower from a Berlin retirement home shows that of the 31 people vaccinated there, some with force and actual violence in the presence of Bundeswehr soldiers, while their (useless) "test" was negative prior to forced vaccinations, 8 people have now died and 11 people have serious side effects. This comes from the AGAPLESION Bethanien Havelgarten retirement home in Berlin-Spandau. There, within four weeks after the first vaccination with the BioNTech/Pfizer vaccine administered, eight of 31 seniors, who suffered from dementia but were in good physical condition according to their age before the vaccination, died.

What is really at stake? To fully understand what is at stake with this new Nuremberg tribunal, to try the greatest crime of all time, we must start with Drosten's lie and the Corman-Drosten paper on the PCR test on behalf of Davos.

'One of the crudest lies in history that has caused an incredible amount of damage and on to which everything hangs. Dan Klaus Schwab, the great architect of this gigantic hostage situation, the sponsors of the financial oligarchy, the politicians at the head of the EU, armed with the implementation of the Drosten and WHO guidelines was what led all Western governments to take the devastating decisions. lockdowns, isolation, containment, curfews, compulsory mask wearing, social distancing and other draconian measures against a non-existent danger". In addition, people have been manipulated by the news media and governments to get vaccinated with an experimental biological agent, based on a lie. If that doesn't work, the governments are moving to force the populations to vaccination with the COVID-19 Immunity and Vaccination Passports, if you don't get the shot, you will lose your freedom to travel.

"These are the truths that will take off the masks of those responsible for the crimes committed," said Dr. Fuellmich. Moreover, to politicians who trusted these corrupt figures, he says: "These facts may be another salvation for them that can help them to put things right and spark the public's long-awaited scholarly debate to avoid being compared and tried with these criminal charlatans, too."

The international legal coalition has become operational this month and has already began.

The Commission is also seeking to take protective measures such as protecting regional agricultural structures, securing a regional currency to avoid a new currency being allocated "from above" and is working to rebuild a new media landscape that provides truly independent information rather than manipulated by the elites that control the news agencies.

This corona crisis, according to all we know today, must be renamed a "Corona Scandal" and those responsible for it must be criminally prosecuted and sued for civil damages. On a political level, everything must be done to make sure that no one will ever again be in a position of such power as to be able to defraud humanity or to attempt to manipulate us with their corrupt agendas. And for this reason I will now explain to you how and where an international network of lawyers will argue this biggest tort case, the corona fraud scandal, which has meanwhile unfolded into probably the greatest crime against humanity ever committed.

'These are the facts that will pull the masks off the faces of all those responsible for these crimes. To the politicians who believe those corrupt people, these facts are hereby offered as a lifeline that can help you readjust your course of action, and start the long overdue public scientific discussion, and not go down with those charlatans and criminals."- Dr.Reiner Fullmich Testimony

Sources: Dr. Reiner Fullmich Testimony

(source)Additional International resources:

Inmedia nl

https://wn.com/Corona_committee/newshttps://rgnpress.ro/…/se-pregateste-al-doilea-tribunal…/http://francesoir.fr/…/interview-me-virginie-de-araujo… de-parisAll seats (41 pieces):https://corona-ausschuss.de/sitzungen/

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More from Reiner Fuellmich and the class lawsuit:

Reiner Fuellmich ~ PCR test fraud lawsuit

https://bitchute.com/video/I0YfRt1Brv5L/

CRIMES AGAINST HUMANITY – Dr. Fuellmich:

https://bitchute.com/video/C6Na6L83BiX8/

DR. FUELLMICH – CORONA-SAMMELKLAGE (GERMAN) CORONA-SCANDAL:

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30TH SITTING CORONA COMMITTEE: PROF. HOCKERTZ, MRNA VACCINES CRIMINAL NEGLIGENCE:

https://bitchute.com/video/EP7DZHhTliBC/

DER FALL DROSTEN – REINER FÜLLMICH:

https://bitchute.com**/video/jzEMQw162APx/

Dr. Fuellmich – Is Dr. Drosten a fraud?

https://bitchute.com/video/hdr29jrGNgMz/

Reference:

https://evolvetoecology.org/2021/02/27/dr-reiner-fuellmich-begins-legal-litigation-on-the-covid-19-fraud-the-greatest-crime-against-humanity/

COMISION
NACIONAL
DE BIOÉTICA

Código de Nuremberg

Normas éticas sobre experimentación en seres humanos

En 1997, el Código de Nüremberg fue publicado el 20 de agosto de 1947, como producto del Juicio de Nüremberg (agosto 1945 a octubre 1946), en el que, junto con la jerarquía nazi, resultaron condenados varios médicos por gravísimos atropellos a los derechos humanos. Dicho texto tiene el mérito de ser el primer documento que planteó explícitamente la obligación de solicitar el Consentimiento Informado, expresión de la autonomía del paciente. Sus recomendaciones son las siguientes:

I. Es absolutamente esencial el consentimiento voluntario del sujeto humano.
II. El experimento debe ser útil para el bien de la sociedad, irremplazable por otros medios de estudio y de la naturaleza que excluya el azar.
III. Basados en los resultados de la experimentación animal y del conocimiento de la historia natural de la enfermedad o de otros problemas en estudio, el experimento debe ser diseñado de tal manera que los resultados esperados justifiquen su desarrollo.
IV. El experimento debe ser ejecutado de tal manera que evite todo sufrimiento físico, mental y daño innecesario.
V. Ningún experimento debe ser ejecutado cuando existan razones a priori para creer que pueda ocurrir la muerte o un daño grave, excepto, quizás en aquellos experimentos en los cuales los médicos experimentadores sirven como sujetos de investigación.
VI. El grado de riesgo a tomar nunca debe exceder el nivel determinado por la importancia humanitaria del problema que pueda ser resuelto por el experimento.
VII. Deben hacerse preparaciones cuidadosas y establecer adecuadas condiciones para proteger al sujeto experimental contra cualquier remota posibilidad de daño, incapacidad y muerte.
VIII. El experimento debe ser conducido solamente por personas científicamente calificadas. Debe requerirse el más alto grado de destreza y cuidado a través de todas las etapas del experimento, a todos aquellos que ejecutan o colaboran en dicho experimento.
IX. Durante el curso del experimento, el sujeto humano debe tener libertad para poner fin al experimento si ha alcanzado el estado físico y mental en el cual parece a él imposible continuarlo.

Durante el curso del experimento, el científico a cargo de él debe estar preparado para terminarlo en cualquier momento, si él cree que en el ejercicio de su buena fe, habilidad superior y juicio cuidadoso, la continuidad del experimento podría terminar en un daño, incapacidad o muerte del sujeto experimental.

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Declaración universal sobre Bioética y Derechos Humanos

19 de octubre de 2005

UNESDOC - (PDF) Inglés - Francés - Español - Ruso - Chino - Arabe

La Conferencia General,

Consciente de la excepcional capacidad que posee el ser humano para reflexionar sobre su propia existencia y su entorno, así como para percibir la injusticia, evitar el peligro, asumir responsabilidades, buscar la cooperación y dar muestras de un sentido moral que dé expresión a principios éticos,

Teniendo en cuenta los rápidos adelantos de la ciencia y la tecnología, que afectan cada vez más a nuestra concepción de la vida y a la vida propiamente dicha, y que han traído consigo una fuerte demanda para que se dé una respuesta universal a los problemas éticos que plantean esos adelantos,

Reconociendo que los problemas éticos suscitados por los rápidos adelantos de la ciencia y de sus aplicaciones tecnológicas deben examinarse teniendo en cuenta no sólo el respeto debido a la dignidad de la persona humana, sino también el respeto universal y la observancia de los derechos humanos y las libertades fundamentales,

Resolviendo que es necesario y conveniente que la comunidad internacional establezca principios universales que sirvan de fundamento para una respuesta de la humanidad a los dilemas y controversias cada vez numerosos que la ciencia y la tecnología plantean a la especie humana y al medio ambiente,

*Recordando*la Declaración Universal de Derechos Humanos del 10 de diciembre de 1948, la Declaración Universal sobre el Genoma Humano y los Derechos Humanos aprobada por la Conferencia General de la UNESCO el 11 de noviembre de 1997 y la Declaración Internacional sobre los Datos Genéticos Humanos aprobada por la Conferencia General de la UNESCO el 16 de octubre de 2003,

*Tomando nota*del Pacto International de Derechos Económicos, Sociales y Culturales y del Pacto Internacional de Derechos Civiles y Políticos adoptados el 16 de diciembre de 1966, la Convención Internacional de las Naciones Unidas sobre la Eliminación de todas las Formas de Discriminación Racial del 21 de diciembre de 1965, la Convención de las Naciones Unidas sobre la eliminación de todas las formas de discriminación contra la mujer del 18 de diciembre de 1979, la Convención de las Naciones Unidas sobre los Derechos del Niño del 20 de noviembre de 1989, el Convenio de las Naciones Unidas sobre la Diversidad Biológica del 5 de junio de 1992, las Normas uniformes de las Naciones Unidas sobre la igualdad de oportunidades para las personas con discapacidad aprobadas por la Asamblea General de las Naciones Unidas en 1993, la Recomendación de la UNESCO relativa a la situación de los investigadores científicos del 20 de noviembre de 1974, la Declaración de la UNESCO sobre la Raza y los Prejuicios Raciales del 27 de noviembre de 1978, la Declaración de la UNESCO sobre las Responsabilidades de las Generaciones Actuales para con las Generaciones Futuras del 12 de noviembre de 1997, la Declaración Universal de la UNESCO sobre la Diversidad Cultural del 2 de noviembre de 2001, el Convenio de la OIT (Nº 169) sobre pueblos indígenas y tribales en países independientes del 27 de junio de 1989, el Tratado Internacional sobre los Recursos Fitogenéticos para la Alimentación y la Agricultura aprobado por la Conferencia de la FAO el 3 de noviembre de 2001 y vigente desde el 29 de junio de 2004, el Acuerdo sobre los aspectos de los derechos de propiedad intelectual relacionados con el comercio (ADPIC) anexo al Acuerdo de Marrakech por el que se establece la Organización Mundial del Comercio y vigente desde el 1º de enero de 1995, la Declaración de Doha relativa al Acuerdo sobre los ADPIC y la salud pública del 14 de noviembre de 2001 y los demás instrumentos internacionales aprobados por las Naciones Unidas y sus organismos especializados, en particular la Organización de las Naciones Unidas para la Agricultura y la Alimentación (FAO) y la Organización Mundial de la Salud (OMS),

Tomando nota asimismo de los instrumentos internacionales y regionales relativos a la bioética, comprendida la Convención para la protección de los derechos humanos y la dignidad del ser humano con respecto a la aplicación de la medicina y la biología – Convención sobre los derechos humanos y la biomedicina del Consejo de Europa, aprobada en 1997 y vigente desde 1999, junto con sus protocolos adicionales, así como las legislaciones y reglamentaciones nacionales en materia de bioética, los códigos de conducta, directrices y otros textos internacionales y regionales sobre bioética, como la Declaración de Helsinki de la Asociación Médica Mundial relativa a los trabajos de investigación biomédica con sujetos humanos, aprobada en 1964 y enmendada sucesivamente en 1975, 1983, 1989, 1996 y 2000, y las Guías éticas internacionales para investigación biomédica que involucra a seres humanos del Consejo de Organizaciones Internacionales de Ciencias Médicas, aprobadas en 1982 y enmendadas en 1993 y 2002,

Reconociendo que esta Declaración se habrá de entender de modo compatible con el derecho internacional y las legislaciones nacionales de conformidad con el derecho relativo a los derechos humanos,

Recordando la Constitución de la UNESCO aprobada el 16 de noviembre de 1945,

Considerando que la UNESCO ha de desempeñar un papel en la definición de principios universales basados en valores éticos comunes que orienten los adelantos científicos y el desarrollo tecnológico y la transformación social, a fin de determinar los desafíos que surgen en el ámbito de la ciencia y la tecnología teniendo en cuenta la responsabilidad de las

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generaciones actuales para con las generaciones venideras, y que las cuestiones de bioética, que forzosamente tienen una dimensión internacional, se deben tratar como un todo, basándose en los principios ya establecidos en la Declaración Universal sobre el Genoma Humano y los Derechos Humanos y la Declaración Internacional sobre los Datos Genéticos Humanos, y teniendo en cuenta no sólo el contexto científico actual, sino también su evolución futura,

Consciente de que los seres humanos forman parte integrante de la biosfera y de que desempeñan un importante papel en la protección del prójimo y de otras formas de vida, en particular los animales,

Reconociendo que, gracias a la libertad de la ciencia y la investigación, los adelantos científicos y tecnológicos han reportado, y pueden reportar, grandes beneficios a la especie humana, por ejemplo aumentando la esperanza de vida y mejorando la calidad de vida, y destacando que esos adelantos deben procurar siempre promover el bienestar de cada individuo, familia, grupo o comunidad y de la especie humana en su conjunto, en el reconocimiento de la dignidad de la persona humana y en el respeto universal y la observancia de los derechos humanos y las libertades fundamentales,

Reconociendo que la salud no depende únicamente de los progresos de la investigación científica y tecnológica sino también de factores psicosociales y culturales,

Reconociendo asimismo que las decisiones relativas a las cuestiones éticas relacionadas con la medicina, las ciencias de la vida y las tecnologías conexas pueden tener repercusiones en los individuos, familias, grupos o comunidades y en la especie humana en su conjunto,

Teniendo presente que la diversidad cultural, fuente de intercambios, innovación y creatividad, es necesaria para la especie humana y, en este sentido, constituye un patrimonio común de la humanidad, pero *destacando* a la vez que no se debe invocar a expensas de los derechos humanos y las libertades fundamentales,

Teniendo presente también que la identidad de una persona comprende dimensiones biológicas, psicológicas, sociales, culturales y espirituales,

Reconociendo que la conducta científica y tecnológica poco ética ha tenido repercusiones especiales en las comunidades indígenas y locales,

Convencida de que la sensibilidad moral y la reflexión ética deberían ser parte integrante del proceso de desarrollo científico y tecnológico y de que la bioética debería desempeñar un papel predominante en las decisiones que han de tomarse ante los problemas que suscita ese desarrollo,

Considerando que es conveniente elaborar nuevos enfoques de la responsabilidad social para garantizar que el progreso de la ciencia y la tecnología contribuye a la justicia y la equidad y sirve el interés de la humanidad,

Reconociendo que una manera importante de evaluar las realidades sociales y lograr la equidad es prestando atención a la situación de la mujer,

Destacando la necesidad de reforzar la cooperación internacional en el ámbito de la bioética, teniendo en cuenta en particular las necesidades específicas de los países en desarrollo, las comunidades indígenas y las poblaciones vulnerables,

Considerando que todos los seres humanos, sin distinción alguna, deberían disfrutar de las mismas normas éticas elevadas en la investigación relativa a la medicina y las ciencias de la vida,

Proclama los siguientes principios y *aprueba*la presente Declaración.

Disposiciones generales

Artículo 1 – Alcance

1. La Declaración trata de las cuestiones éticas relacionadas con la medicina, las ciencias de la vida y las tecnologías conexas aplicadas a los seres humanos, teniendo en cuenta sus dimensiones sociales, jurídicas y ambientales.

2. La Declaración va dirigida a los Estados. Imparte también orientación, cuando procede, para las decisiones o prácticas de individuos, grupos, comunidades, instituciones y empresas, públicas y privadas.

Artículo 2 – Objetivos

Los objetivos de la presente Declaración son:

a) proporcionar un marco universal de principios y procedimientos que sirvan de guía a los Estados en la formulación de legislaciones, políticas u otros instrumentos en el ámbito de la bioética;

b) orientar la acción de individuos, grupos, comunidades, instituciones y empresas, públicas y privadas;

c) promover el respeto de la dignidad humana y proteger los derechos humanos, velando por el respeto de la vida de los seres humanos y las libertades fundamentales, de conformidad con el derecho internacional relativo a los derechos humanos;

d) reconocer la importancia de la libertad de investigación científica y las repercusiones beneficiosas del desarrollo científico y tecnológico, destacando al mismo tiempo la necesidad de que esa investigación y los consiguientes adelantos se realicen en el marco de los principios éticos enunciados en esta Declaración y respeten la dignidad humana, los derechos humanos y las libertades fundamentales;

e) fomentar un diálogo multidisciplinario y pluralista sobre las cuestiones de bioética entre todas las partes interesadas y dentro de la sociedad en su conjunto;

f) promover un acceso equitativo a los adelantos de la medicina, la ciencia y la tecnología, así como la más amplia circulación posible y un rápido aprovechamiento compartido de los conocimientos relativos a esos adelantos y de sus correspondientes beneficios, prestando una especial atención a las necesidades de los países en desarrollo;

g) salvaguardar y promover los intereses de las generaciones presentes y venideras;

h) destacar la importancia de la biodiversidad y su conservación como preocupación común de la especie humana.

Principios

En el ámbito de la presente Declaración, tratándose de decisiones adoptadas o de prácticas ejecutadas por aquellos a quienes va dirigida, se habrán de respetar los principios siguientes.

Artículo 3 – Dignidad humana y derechos humanos

1. Se habrán de respetar plenamente la dignidad humana, los derechos humanos y las libertades fundamentales.
2. Los intereses y el bienestar de la persona deberían tener prioridad con respecto al interés exclusivo de la ciencia o la sociedad.

Artículo 4 – Beneficios y efectos nocivos

Al aplicar y fomentar el conocimiento científico, la práctica médica y las tecnologías conexas, se deberían potenciar al máximo los beneficios directos e indirectos para los pacientes, los participantes en las actividades de investigación y otras personas concernidas, y se deberían reducir al máximo los posibles efectos nocivos para dichas personas.

Artículo 5 – Autonomía y responsabilidad individual

Se habrá de respetar la autonomía de la persona en lo que se refiere a la facultad de adoptar decisiones, asumiendo la responsabilidad de éstas y respetando la autonomía de los demás. Para las personas que carecen de la capacidad de ejercer su autonomía, se habrán de tomar medidas especiales para proteger sus derechos e intereses.

Artículo 6 – Consentimiento

1. Toda intervención médica preventiva, diagnóstica y terapéutica sólo habrá de llevarse a cabo previo consentimiento libre e informado de la persona interesada, basado en la información adecuada. Cuando proceda, el consentimiento debería ser expreso y la persona interesada podrá revocarlo en todo momento y por cualquier motivo, sin que esto entrañe para ella desventaja o perjuicio alguno.

2. La investigación científica sólo se debería llevar a cabo previo consentimiento libre, expreso e informado de la persona interesada. La información debería ser adecuada, facilitarse de forma comprensible e incluir las modalidades para la revocación del consentimiento. La persona interesada podrá revocar su consentimiento en todo momento y por cualquier motivo, sin que esto entrañe para ella desventaja o perjuicio alguno. Las excepciones a este principio deberían hacerse únicamente de conformidad con las normas éticas y jurídicas aprobadas por los Estados, de forma compatible con los principios y disposiciones enunciados en la presente Declaración, en particular en el Artículo 27, y con el derecho internacional relativo a los derechos humanos.

3. En los casos correspondientes a investigaciones llevadas a cabo en un grupo de personas o una comunidad, se podrá pedir además el acuerdo de los representantes legales del grupo o la comunidad en cuestión. El acuerdo colectivo de una comunidad o el consentimiento de un dirigente comunitario u otra autoridad no deberían sustituir en caso alguno el consentimiento informado de una persona.

Artículo 7 – Personas carentes de la capacidad de dar su consentimiento

De conformidad con la legislación nacional, se habrá de conceder protección especial a las personas que carecen de la capacidad de dar su consentimiento:

a) la autorización para proceder a investigaciones y prácticas médicas debería obtenerse conforme a los intereses de la persona interesada y de conformidad con la legislación nacional. Sin embargo, la persona interesada debería estar asociada en la mayor medida posible al proceso de adopción de la decisión de consentimiento, así como al de su revocación;

b) se deberían llevar a cabo únicamente actividades de investigación que redunden directamente en provecho de la salud de la persona interesada, una vez obtenida la autorización y reunidas las condiciones de protección prescritas por la ley, y si no existe una alternativa de investigación de eficacia comparable con participantes en la investigación capaces de dar su consentimiento. Las actividades de investigación que no entrañen un posible beneficio directo para la salud se deberían llevar a cabo únicamente de modo excepcional, con las mayores restricciones, exponiendo a la persona únicamente a un riesgo y una coerción mínimos y, si se espera que la investigación redunde en provecho de la salud de otras personas de la misma categoría, a reserva de las condiciones prescritas por la ley y de forma compatible con la protección de los derechos humanos de la persona. Se debería respetar la negativa de esas personas a tomar parte en actividades de investigación.

Artículo 8 – Respeto de la vulnerabilidad humana y la integridad personal

Al aplicar y fomentar el conocimiento científico, la práctica médica y las tecnologías conexas, se debería tener en cuenta la vulnerabilidad humana. Los individuos y grupos especialmente vulnerables deberían ser protegidos y se debería respetar la integridad personal de dichos individuos.

Artículo 9 – Privacidad y confidencialidad

La privacidad de las personas interesadas y la confidencialidad de la información que les atañe deberían respetarse. En la mayor medida posible, esa información no debería utilizarse o revelarse para fines distintos de los que determinaron su acopio o para los que se obtuvo el consentimiento, de conformidad con el derecho internacional, en particular el relativo a los derechos humanos.

Artículo 10 – Igualdad, justicia y equidad

Se habrá de respetar la igualdad fundamental de todos los seres humanos en dignidad y derechos, de tal modo que sean tratados con justicia y equidad.

Artículo 11 – No discriminación y no estigmatización

Ningún individuo o grupo debería ser sometido por ningún motivo, en violación de la dignidad humana, los derechos humanos y las libertades fundamentales, a discriminación o estigmatización alguna.

Artículo 12 – Respeto de la diversidad cultural y del pluralismo

Se debería tener debidamente en cuenta la importancia de la diversidad cultural y del pluralismo. No obstante, estas consideraciones no habrán de invocarse para atentar contra la dignidad humana, los derechos humanos y las libertades fundamentales o los principios enunciados en la presente Declaración, ni tampoco para limitar su alcance.

Artículo 13 – Solidaridad y cooperación

Se habrá de fomentar la solidaridad entre los seres humanos y la cooperación internacional a este efecto.

Artículo 14 – Responsabilidad social y salud

1. La promoción de la salud y el desarrollo social para sus pueblos es un cometido esencial de los gobiernos, que comparten todos los sectores de la sociedad.

2. Teniendo en cuenta que el goce del grado máximo de salud que se pueda lograr es uno de los derechos fundamentales de todo ser humano sin distinción de raza, religión, ideología política o condición económica o social, los progresos de la ciencia y la tecnología deberían fomentar:

a) el acceso a una atención médica de calidad y a los medicamentos esenciales, especialmente para la salud de las mujeres y los niños, ya que la salud es esencial para la vida misma y debe considerarse un bien social y humano;

b) el acceso a una alimentación y un agua adecuadas;

c) la mejora de las condiciones de vida y del medio ambiente;

d) la supresión de la marginación y exclusión de personas por cualquier motivo; y

e) la reducción de la pobreza y el analfabetismo.

Artículo 15 – Aprovechamiento compartido de los beneficios

1. Los beneficios resultantes de toda investigación científica y sus aplicaciones deberían compartirse con la sociedad en su conjunto y en el seno de la comunidad internacional, en particular con los países en desarrollo. Los beneficios que se deriven de la aplicación de este principio podrán revestir las siguientes formas:

a) asistencia especial y duradera a las personas y los grupos que hayan tomado parte en la actividad de investigación y reconocimiento de los mismos;

b) acceso a una atención médica de calidad;

c) suministro de nuevas modalidades o productos de diagnóstico y terapia obtenidos gracias a la investigación;

d) apoyo a los servicios de salud;

e) acceso a los conocimientos científicos y tecnológicos;

f) instalaciones y servicios destinados a crear capacidades en materia de investigación;

g) otras formas de beneficio compatibles con los principios enunciados en la presente Declaración.

2. Los beneficios no deberían constituir incentivos indebidos para participar en actividades de investigación.

Artículo 16 – Protección de las generaciones futuras

Se deberían tener debidamente en cuenta las repercusiones de las ciencias de la vida en las generaciones futuras, en particular en su constitución genética.

Artículo 17 – Protección del medio ambiente, la biosfera y la biodiversidad

Se habrán de tener debidamente en cuenta la interconexión entre los seres humanos y las demás formas de vida, la importancia de un acceso apropiado a los recursos biológicos y genéticos y su utilización, el respeto del saber tradicional y el papel de los seres humanos en la protección del medio ambiente, la biosfera y la biodiversidad.

Aplicación de los principios

Artículo 18 – Adopción de decisiones y tratamiento de las cuestiones bioéticas

1 Se debería promover el profesionalismo, la honestidad, la integridad y la transparencia en la adopción de decisiones, en particular las declaraciones de todos los conflictos de interés y el aprovechamiento compartido de conocimientos. Se debería procurar utilizar los mejores conocimientos y métodos científicos disponibles para tratar y examinar periódicamente las cuestiones de bioética.

2. Se debería entablar un diálogo permanente entre las personas y los profesionales interesados y la sociedad en su conjunto.

3. Se deberían promover las posibilidades de un debate público pluralista e informado, en el que se expresen todas las opiniones pertinentes.

Artículo 19 – Comités de ética

Se deberían crear, promover y apoyar, al nivel que corresponda, comités de ética independientes, pluridisciplinarios y pluralistas con miras a:

a) evaluar los problemas éticos, jurídicos, científicos y sociales pertinentes suscitados por los proyectos de investigación relativos a los seres humanos;

b) prestar asesoramiento sobre problemas éticos en contextos clínicos;

c) evaluar los adelantos de la ciencia y la tecnología, formular recomendaciones y contribuir a la preparación de orientaciones sobre las cuestiones que entren en el ámbito de la presente Declaración;

d) fomentar el debate, la educación y la sensibilización del público sobre la bioética, así como su participación al respecto.

Artículo 20 – Evaluación y gestión de riesgos

Se deberían promover una evaluación y una gestión apropiadas de los riesgos relacionados con la medicina, las ciencias de la vida y las tecnologías conexas.

Artículo 21 – Prácticas transnacionales

1. Los Estados, las instituciones públicas y privadas y los profesionales asociados a actividades transnacionales deberían procurar velar por que sea conforme a los principios enunciados en la presente Declaración toda actividad que entre en el ámbito de ésta y haya sido realizada, financiada o llevada a cabo de cualquier otra manera, en su totalidad o en parte, en distintos Estados.

2. Cuando una actividad de investigación se realice o se lleve a cabo de cualquier otra manera en un Estado o en varios (el Estado anfitrión o los Estados anfitriones) y sea financiada por una fuente ubicada en otro Estado, esa actividad debería someterse a un nivel apropiado de examen ético en el Estado anfitrión o los Estados anfitriones, así como en el Estado donde esté ubicada la fuente de financiación. Ese examen debería basarse en normas éticas y jurídicas que sean compatibles con los principios enunciados en la presente Declaración.

3. Las actividades de investigación transnacionales en materia de salud deberían responder a las necesidades de los países anfitriones y se debería reconocer que es importante que la investigación contribuya a la paliación de los problemas urgentes de salud a escala mundial.

4. Al negociar un acuerdo de investigación, se deberían establecer las condiciones de colaboración y el acuerdo sobre los beneficios de la investigación con la participación equitativa de las partes en la negociación.

5. Los Estados deberían tomar las medidas adecuadas en los planos nacional e internacional para luchar contra el bioterrorismo, así como contra el tráfico ilícito de órganos, tejidos, muestras, recursos genéticos y materiales relacionados con la genética.

Promoción de la declaración

Artículo 22 – Función de los Estados

1. Los Estados deberían adoptar todas las disposiciones adecuadas, tanto de carácter legislativo como administrativo o de otra índole, para poner en práctica los principios enunciados en la presente Declaración, conforme al derecho internacional relativo a los derechos humanos. Esas medidas deberían ser secundadas por otras en los terrenos de la educación, la formación y la información pública.

2. Los Estados deberían alentar la creación de comités de ética independientes, pluridisciplinarios y pluralistas, tal como se dispone en el Artículo 19.

Artículo 23 – Educación, formación e información en materia de bioética

1. Para promover los principios enunciados en la presente Declaración y entender mejor los problemas planteados en el plano de la ética por los adelantos de la ciencia y la tecnología, en particular para los jóvenes, los Estados deberían esforzarse no sólo por fomentar la educación y formación relativas a la bioética en todos los planos, sino también por estimular los programas de información y difusión de conocimientos sobre la bioética.

2. Los Estados deberían alentar a las organizaciones intergubernamentales internacionales y regionales, así como a las organizaciones no gubernamentales internacionales, regionales y nacionales, a que participen en esta tarea.

Artículo 24 – Cooperación internacional

1. Los Estados deberían fomentar la difusión de información científica a nivel internacional y estimular la libre circulación y el aprovechamiento compartido de los conocimientos científicos y tecnológicos.

2. En el contexto de la cooperación internacional, los Estados deberían promover la cooperación científica y cultural y llegar a acuerdos bilaterales y multilaterales que permitan a los países en desarrollo crear las capacidades necesarias para participar en la creación y el intercambio de conocimientos científicos y de las correspondientes competencias técnicas, así como en el aprovechamiento compartido de sus beneficios.

3. Los Estados deberían respetar y fomentar la solidaridad entre ellos y deberían también promoverla con y entre individuos, familias, grupos y comunidades, en particular con los que son más vulnerables a causa de enfermedades, discapacidades u otros factores personales, sociales o ambientales, y con los que poseen recursos más limitados.

Artículo 25 – Actividades de seguimiento de la UNESCO

1. La UNESCO deberá promover y difundir los principios enunciados en la presente Declaración. Para ello, la UNESCO solicitará la ayuda y la asistencia del Comité Intergubernamental de Bioética (CIGB) y del Comité Internacional de Bioética (CIB).

2. La UNESCO deberá reiterar su voluntad de tratar la bioética y de promover la colaboración entre el CIGB y el CIB.

Disposiciones finales

Artículo 26 – Interrelación y complementariedad de los principios

La presente Declaración debe entenderse como un todo y los principios deben entenderse como complementarios y relacionados unos con otros. Cada principio debe considerarse en el contexto de los demás principios, según proceda y corresponda a las circunstancias.

Artículo 27 –Limitaciones a la aplicación de los principios

Si se han de imponer limitaciones a la aplicación de los principios enunciados en la presente Declaración, se debería hacer por ley, en particular las leyes relativas a la seguridad pública para investigar, descubrir y enjuiciar delitos, proteger la salud pública y salvaguardar los derechos y libertades de los demás. Dicha ley deberá ser compatible con el derecho internacional relativo a los derechos humanos.

Artículo 28 – Salvedad en cuanto a la interpretación: actos que vayan en contra de los derechos humanos, las libertades fundamentales y la dignidad humana

Ninguna disposición de la presente Declaración podrá interpretarse como si confiriera a un Estado, grupo o individuo derecho alguno a emprender actividades o realizar actos que vayan en contra de los derechos humanos, las libertades fundamentales y la dignidad humana.

http://portal.unesco.org/es/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

Monday March 29, 2021

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WHO Chief Tedros Adhanom Accused of Genocide

World Health Organization (WHO) Director-General Tedros Adhanom Ghebreyesus attends a daily press briefing on COVID-19 virus at the WHO headquaters on March 9, 2020 in Geneva. (FABRICE COFFRINI/AFP via Getty Images)

By Theodore Bunker | Monday, 14 December 2020 10:27 AM

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American economist David Steinman is calling for Tedros Adhanom Ghebreyesus, the head of the World Health

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Organization, to be prosecuted for genocide over his alleged actions in Ethiopia, The Times reports.

Steinman, who was nominated for the Nobel peace prize last year, has filed a complaint with the International Criminal Court in The Hague accusing Tedros of being one of the officials in charge of Ethiopia's security services from 2013-2015, during the time when he was the country's foreign minister as a member of the Tigray People's Liberation Front party.

Tedros, whose background is in biology and research, became the first person without medical qualifications to lead the WHO in 2017.

According to Steinman, Tedros "was a crucial decision maker in relation to security service actions that included killing, arbitrarily detaining and torturing Ethiopians." He goes on to accuse Tedros of supervising the "killing, and causing serious bodily and mental harm to, members of the Amhara, Konso, Oromo and Somali tribes with intent to destroy those tribes in whole or in part."

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Steinman, who previously served as a consultant to the U.S. National Security Council and as an adviser to Ethiopia's democracy movement for almost three decades, noted in his complaint that a U.S. government report from 2016 noted that the country's "civilian authorities at times did not maintain control over the security forces, and local police in rural areas and local militias sometimes acted independently."

Last month, the chief of staff to the Ethiopian army, Gen. Berhanu Jula, called on Tedros to resign after accusing him of attempting to obtain weapons for the Tigray region, where local forces are currently fighting the Ethiopian army.

Tedros has denied the general's claim that he is involved in the fighting in Tigray, along with all other allegations of misconduct.

"There have been reports suggesting I am taking sides in this situation," he said in a statement. "This is not true and I want to say that I am on only one side and that is the side of peace".

Related Stories:

- **Ethiopia Accuses WHO Chief of Backing Defiant Tigray Region**
- **WHO Chief: World May be Tired, but Virus 'Not Tired of Us'**

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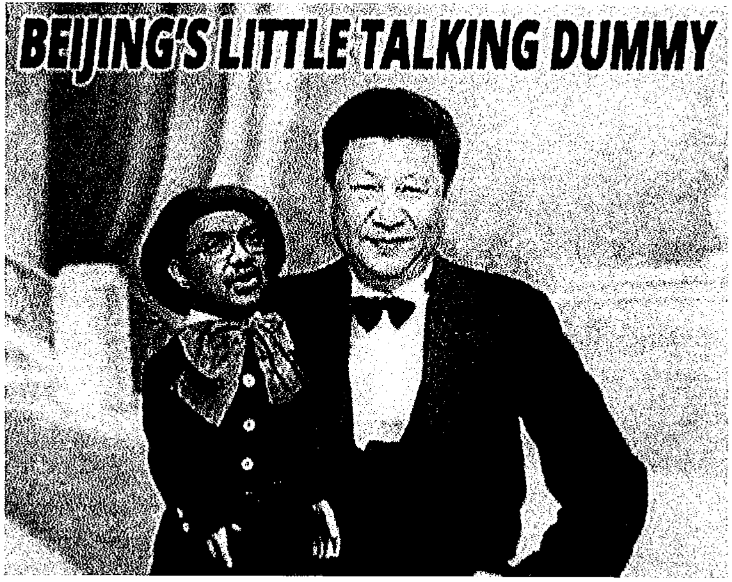

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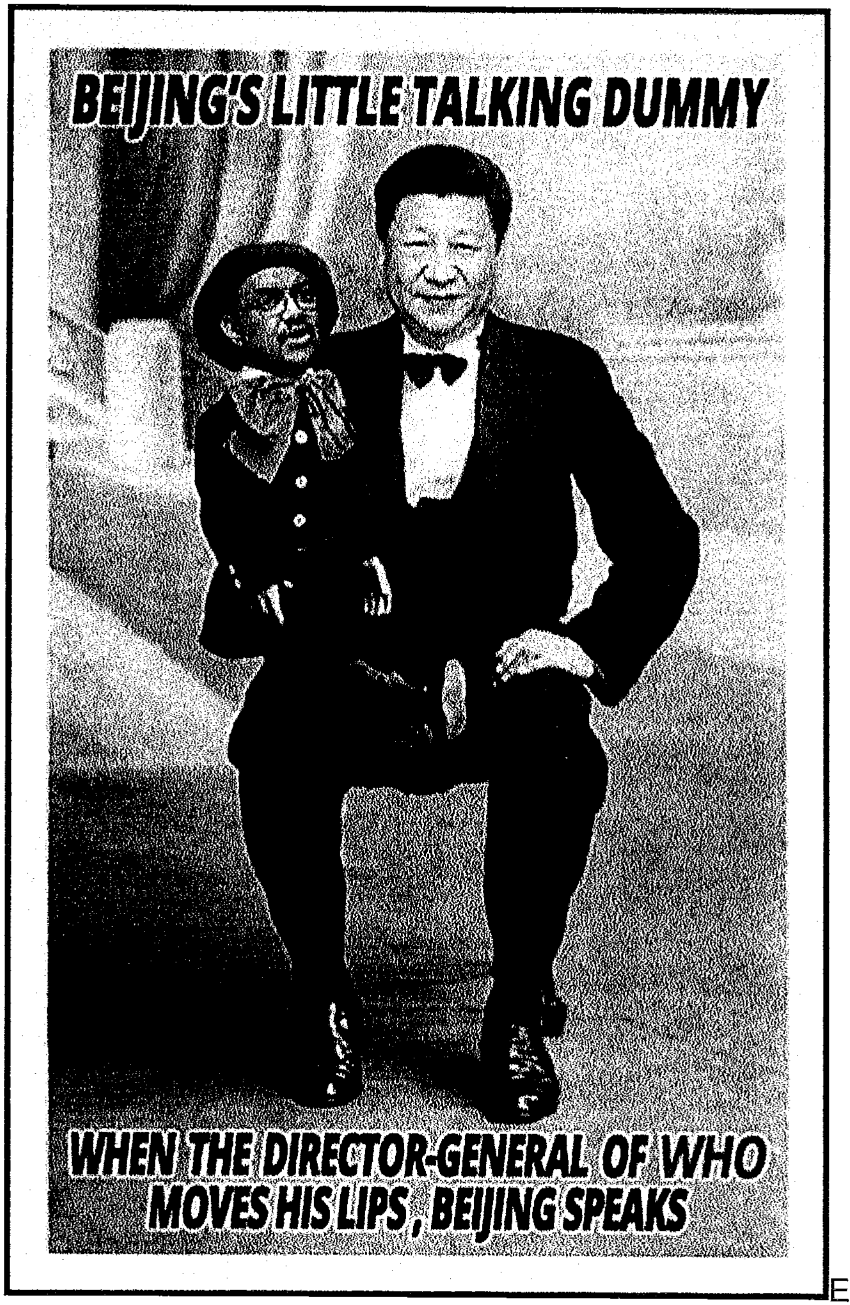
When Tedros Moves His Lips, Beijing Speaks

By Yaacov Apelbaum | March 23, 2020

[UPDATED (courtesy of Yaacov Apelbaum) with static images in lieu of some links, which are often subject to vanishing into the abyss of virtual space.]

On February 15, 2020, the director-general of the World Health Organization (WHO), Tedros Adhanom Ghebreyesus, addressed the Munich Security Conference. At that time, there were only about 60K cases of COVID-19 in China and about 500 in the rest of the world. Tedros was more concerned with misinformation than with containment. In his address, he said:

“We’re not just fighting an epidemic; we’re fighting an infodemic. Fake news spreads faster and more easily than this virus, and is just as dangerous.” And if we don’t tackle this, he went on, “we are headed down a dark path that leads nowhere but division and disharmony.”


BEIJING'S LITTLE TALKING DUMMY
WHEN THE DIRECTOR-GENERAL OF WHO MOVES HIS LIPS, BEIJING SPEAKS

Even if Tedros was just moving his lips while the ministry of propaganda back in Beijing was doing the actual talking, truer words about the "dark path" have never been spoken. The whole COVID-19 affair with its inflated high mortality rates (currently claimed by the WHO to be 3.9% when in actuality it's less than 0.5%), artificial shortage to PPE (it exists, it's just being diverted away from the US by the Chinese), and incendiary MSM coverage, is an information warfare campaign and China is using Tedros and the MSM as a delivery vector.

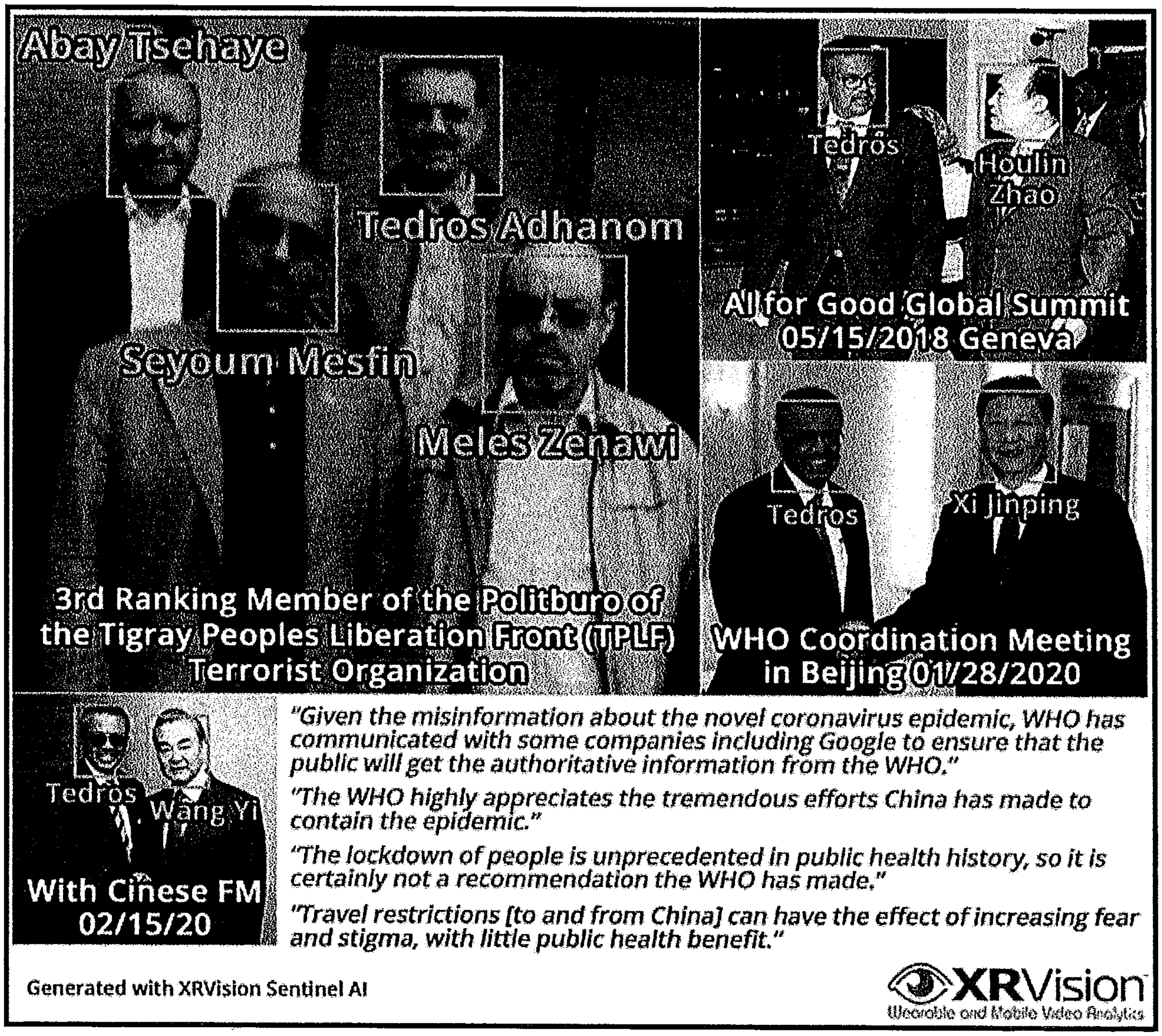
A Profile of a Chinese Enabler

Tedros was voted WHO director-general in 2017, replacing another incompetent Chinese medical prodigy, Dr. Margaret Chan. Tedros is the first WHO director-general without a medical degree. He also has the worst job qualifications in the written history of employment.

Tedros got his bachelors degree in biology from the University of Asmara in Eritrea. After his graduation, he served in a junior position at the Ministry of Health under the Marxist dictatorship of Mengistu. After the fall of Mengistu in 1991, he showed up in the UK and got a masters degree in Immunology of Infectious Diseases from the University of London. In 2000, he got a PhD in Community Health from the University of Nottingham. His dissertation was titled: "*The effects of dams on malaria transmission in Tigray Region, northern Ethiopia.*" From the writing style analysis of the treatise, it is unlikely that he wrote his own dissertation.

Just like another clueless British sponsored PhD, Joseph Mifsud, Tedros's subsidized academic pedigree also hints of political grooming. This plan apparently derailed when Tedros chose to become a Chinese client instead of continuing to pay homage to his old (and cash-strapped) patrons at the British Foreign and Commonwealth Office.

From 2005-2012, under Prime Minister Meles Zenawi, Tedros was the Minister of Health. During his tenure, he covered-up one of the worst outbreaks of cholera in Ethiopian history. Between 2012-2016, he was the Ethiopian foreign minister and was involved in the violent suppression and starvation of the rival Amhara clan. A little known biographical detail about Tedros is that he was the 3rd ranking member of the politburo of the Tigray Peoples Liberation Front (TPLF) Terrorist Organization.


Abay Tsehaye
Tedros Adhanom
Seyoum Mesfin
Meles Zenawi
3rd Ranking Member of the Politburo of the Tigray Peoples Liberation Front (TPLF) Terrorist Organization
Tedros
Houlin Zhao
All for Good Global Summit 05/15/2018 Geneva
Tedros
Xi Jinping
WHO Coordination Meeting in Beijing 01/28/2020
Tedros
Wang Yi
With Cinese FM 02/15/20
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"Given the misinformation about the novel coronavirus epidemic, WHO has communicated with some companies including Google to ensure that the public will get the authoritative information from the WHO."

"The WHO highly appreciates the tremendous efforts China has made to contain the epidemic."

"The lockdown of people is unprecedented in public health history, so it is certainly not a recommendation the WHO has made."

"Travel restrictions [to and from China] can have the effect of increasing fear and stigma, with little public health benefit."

Image 1: Tedros, his FPLF linkage, and his full-time job as China's propaganda mouthpiece

Tedros's rapid rise to the top of the directorship of the WHO began after his collaboration with Bill Gates and the Clinton Foundation and its CHAI initiative. Running some analytics on Tedros's activity between 1991-2018 shows conduct riddled with fraud, corruption, the worst forms of human rights abuses, and scandals.

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Image 2: Tedros with his power base

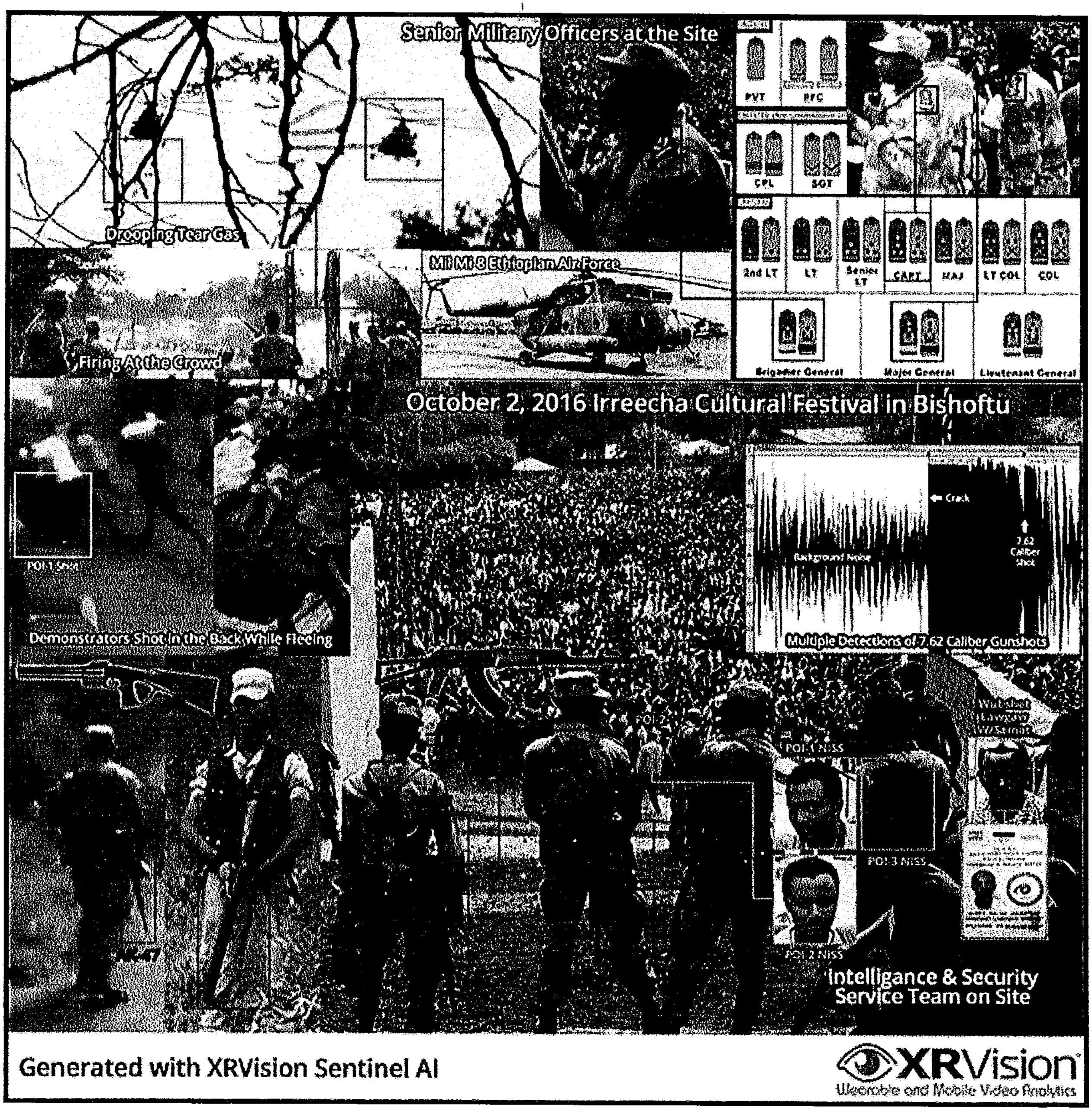
Senior Military Officers at the Site
PVT
PFC
CPL
SGT
2nd LT
LT
Senior LT
CAPT
MAJ
LT COL
COL
Brigadier General
Major General
Lieutenant General
Drooping Tear Gas
Mil Mi-8 Ethiopian Air Force
Firing At the Crowd
October 2, 2016 Irreecha Cultural Festival in Bishoftu
POI-1 Shot
Demonstrators Shot in the Back While Fleeing
Crack
Background Noise
7.62 Caliber Shot
Multiple Detections of 7.62 Caliber Gunshots
AK-47
POI-2
POI-1 NISS
POI-3 NISS
POI-2 NISS
Intelligence & Security Service Team on Site
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Image 3: Tedros lying about the Ethiopian police/army being unarmed and not firing and attacking the crowd at the Irreecha cultural festival in Bishoftu on October 2, 2016. "*Indeed, it is quite clear from the videos that there was no shooting and the police were unarmed.*"

Glaring character flaws and dishonesty aside, an interesting point of convergence between Tedros, China, and the COVID-19 pandemic is that Ethiopia received billions of dollars in Chinese aid over the past few years. Tedros has personally benefited from this aid in the form of several well-padded foreign bank accounts. In this context, it doesn't take much effort to figure out why he advised Ethiopian Airlines to continue to fly daily from major Chinese cities. This is while 59 other air carriers from 44 different countries all grounded their flights to and from China. Ethiopian Airlines still insists that it will follow directives from the WHO and continue its daily China flights.

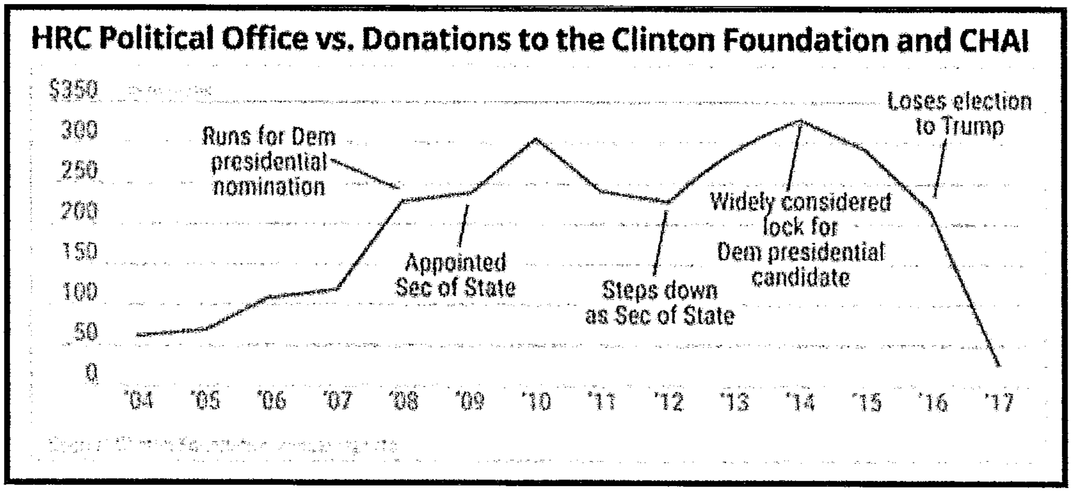
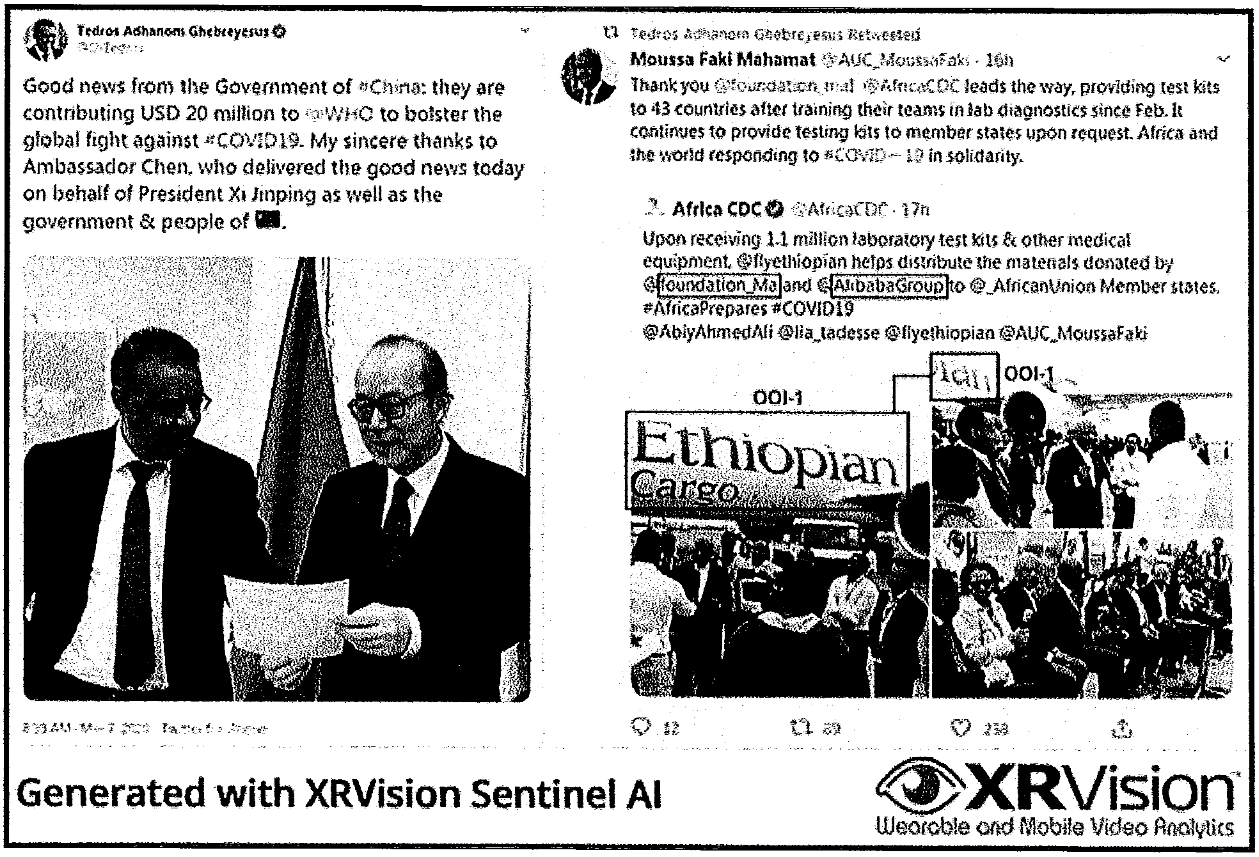


Image 4: HRC political office vs. donations to the Clinton Foundation. In 2016, Tedros brokered a $100 million donation to the Clinton foundation. Within a few months, he became the director-general of the WHO. In 2017, Bill Clinton described Tedros as "*one of the ablest public servants I ever worked with.*"

In terms of the Chinese logistical involvement in making this epidemic pandemic, it just happens that they financed and built the international airport in Addis Ababa. This airport is the 'gateway' for travel between China and Africa. It is also a major hub for European and US traffic. Ethiopia's Bole airport sees, on average, 1500 passengers per day arriving from China.



Tedros Adhanom Ghebreyesus

Good news from the Government of #China: they are contributing USD 20 million to @WHO to bolster the global fight against #COVID19. My sincere thanks to Ambassador Chen, who delivered the good news today on behalf of President Xi Jinping as well as the government & people of .

Tedros Adhanom Ghebreyesus Retweeted

Moussa Faki Mahamat @AUC_MoussaFaki · 16h

Thank you @foundation_ma! @AfricaCDC leads the way, providing test kits to 43 countries after training their teams in lab diagnostics since Feb. It continues to provide testing kits to member states upon request. Africa and the world responding to #COVID-19 in solidarity.

Africa CDC @AfricaCDC · 17h

Upon receiving 1.1 million laboratory test kits & other medical equipment, @flyethiopian helps distribute the materials donated by @foundation_Ma and @AlibabaGroup to @_AfricanUnion Member states. #AfricaPrepares #COVID19
@AbiyAhmedAli @lia_tadesse @flyethiopian @AUC_MoussaFaki

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Image 5: Thank you China for 'bolstering the fight against COVID19', giving the MHO 20 million dollars, and providing its African clients with endless supply of PPE.

Any discussion about the emerging Chinese infodemic narrative, their latest western influence operations, and the WHO complacency in this activity should be viewed through these Tedros related statements:

<ins>On using Google and SM to suppress counter WHO narrative</ins>

"Given the misinformation about the novel coronavirus epidemic, WHO has communicated with some companies including Google to ensure that the public will get the authoritative information from the WHO."

On international travel restriction to and from China

"Travel restrictions [to and from China] can have the effect of increasing fear and stigma, with little public health benefit."

On quarantine requirements for the sick

"The lockdown of people is unprecedented in public health history, so it is certainly not a recommendation the WHO has made."

On spreading official Chinese government propaganda

"The WHO highly appreciates the tremendous efforts China has made to contain the epidemic."

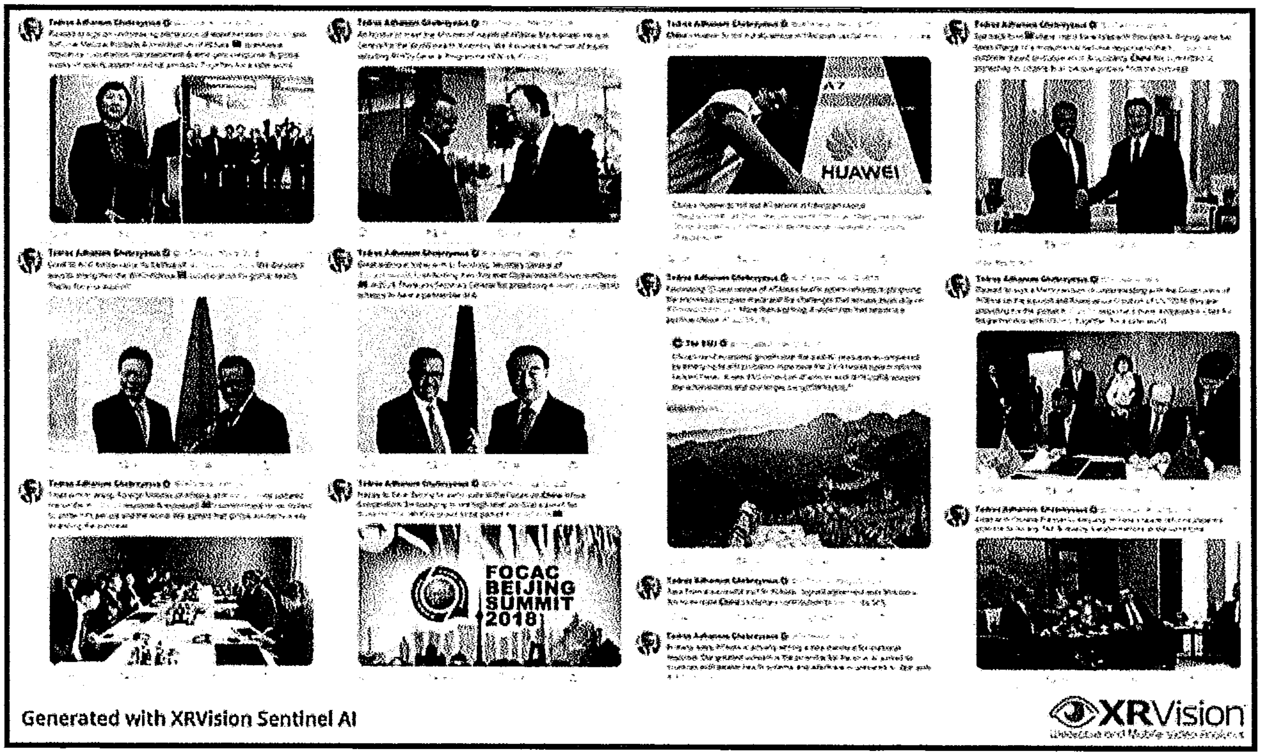

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Image 6: Tedros Adhanom Ghebreyesus, 'All good things come from China'

Where is the COVID-19 Messaging Coming From?

The majority of the aggressive narrative regarding the lethality of the COVID-19 pandemic and it's apocalyptic nature is coming from the WHO and a related international network of activist, politicians, high-tech guys, and reporters. A large number of these 'activists' are US based MSM journalists. Running some SIGINT on the sources of the messaging shows clear signs of 4C activity, timing, and a publication strategy. Not surprisingly, the main stated objective in many of these communications is the political targeting of the Trump administration. It is also of note that some of these individuals include politicians, who have been discussing the need and working on the development of 'scientific eye candy' to support the predictions of a zombie apocalypse. If you still doubt that this is a coordinated campaign, here is a sampling of the massaging topics that the 'COVID-19 network' has generated over the past 10 weeks:

- Trump has made America a failed state and a third world country
- The 'Jewish involvement' in the COVID-19 pandemic
- Stock market is collapsing and people will lose all their savings
- Hospitals will be overwhelmed
- The reason for PPE shortage in the US is the Trump administration
- The Corona virus infects and kills both young and old at the same rate
- Trump is doing nothing to stop the spread of the virus
- Reference to the Chinese origin of virus is racist and xenophobic
- The Chinese have done everything to combat the pandemic
- Trump will declare martial law and eliminate the 2020 elections
- Need to mobilize Web 2.0 platforms and SMEs to support the narrative

The following is a sampling of three profiles of member of the 'COVID-19 network' of contributors from outlets like WaPo, NYT, and the foreign media.

Brian Klass WaPo Reporter and Agent Saboteur Extraordinaire

Brian Klass is an American originally from Minnesota who lives and works in the UK. He is governor Mark Dayton's former driver. He received his BA from Carleton College, a masters degree in Politics Science from Oxford, and his PhD in Comparative

Government from Oxford. He has worked with Soros affiliated organizations and has ties to the British IC. He is a fellow in the department of global politics at the London School of Economics, an assistant professor of global politics at University College London, and a reporter for The Washington Post.

Image 7: Brian Klass in his own words

Klass knows several of the key players in the Steele Dossier such as Luke Harding and Ellen Nakashima (the reporter behind the allegation that the Russians hacked/leaked the DNC emails). Klass is a frequent television commentator and democratic political consultant, a US campaign adviser, and political analyst of US and foreign policy in mainstream media outlets like CNN, MSNBC, and CBS. He is an author of "The Despot's Apprentice: Donald Trump's Attack on Democracy", the "The Despot's Accomplice: How the West is Aiding and Abetting the Decline of Democracy", and the Co-Author of "How to Rig an Election".

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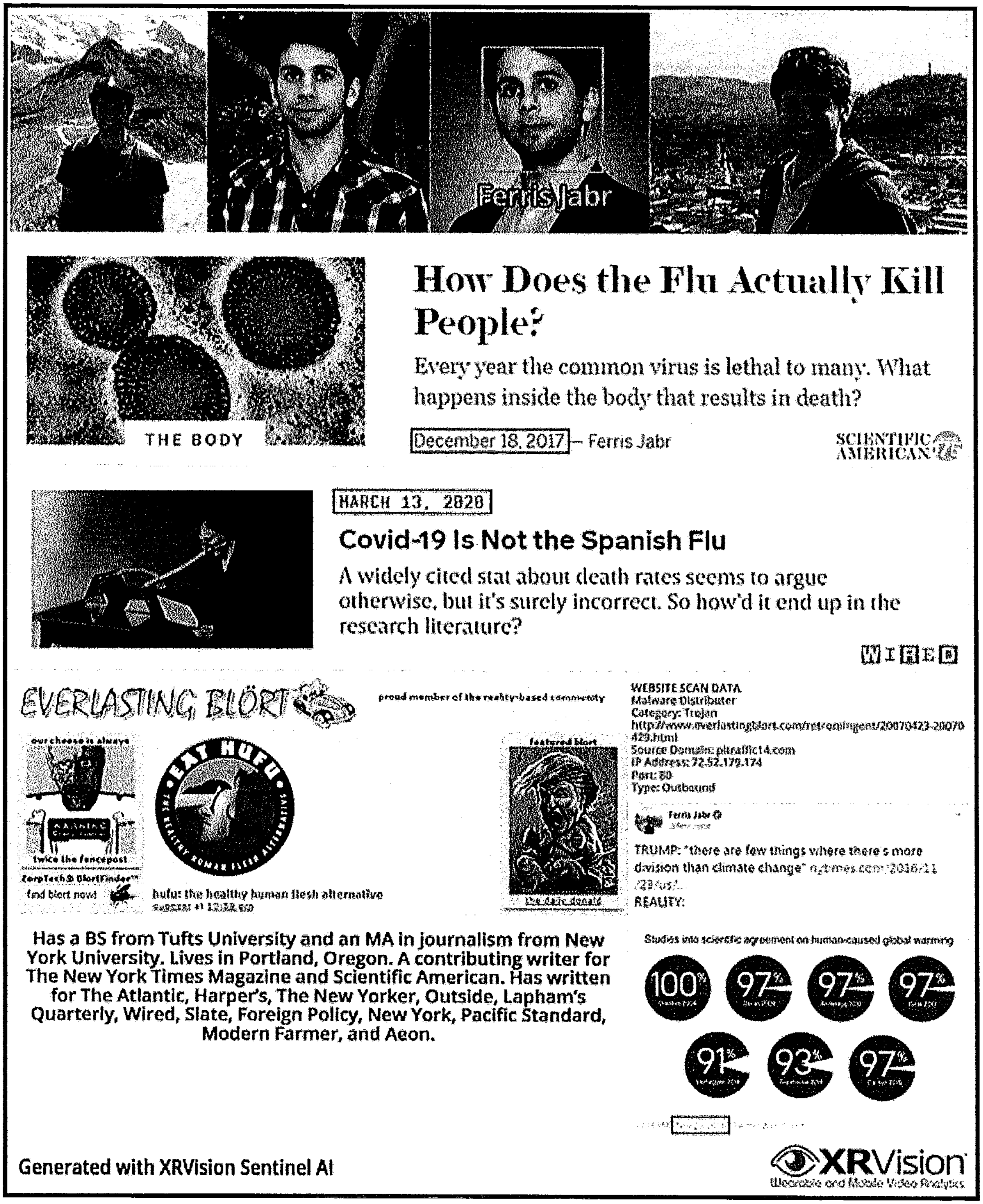
Brian Klaas

After Trump attempted to punish Brennan for political reasons—something that happens in authoritarian regimes, not democracies—Brennan pens a damning op-ed, which (again) destroys Trump's false claim that there was "no collusion." There was a conspiracy.

Image 8: Brian Klass, sample of his linkage and political MSM activity


Ferris Jabr
THE BODY
SCIENTIFIC AMERICAN
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How Does the Flu Actually Kill People?

Every year the common virus is lethal to many. What happens inside the body that results in death?

December 18, 2017 – Ferris Jabr

MARCH 13, 2020

Covid-19 Is Not the Spanish Flu

A widely cited stat about death rates seems to argue otherwise, but it's surely incorrect. So how'd it end up in the research literature?

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Port: 80
Type: Outbound

Ferris Jabr

TRUMP: "there are few things where there's more division than climate change" nytimes.com/2016/11/23/us/...
REALITY:

Has a BS from Tufts University and an MA in journalism from New York University. Lives in Portland, Oregon. A contributing writer for The New York Times Magazine and Scientific American. Has written for The Atlantic, Harper's, The New Yorker, Outside, Lapham's Quarterly, Wired, Slate, Foreign Policy, New York, Pacific Standard, Modern Farmer, and Aeon.

Studies into scientific agreement on human-caused global warming
100%
97%
97%
97%
91%
93%
97%

Generated with XRVision Sentinel AI

XRVision
Wearable and Mobile Video Analytics

Image 9: The profile of Ferris Jabr, the 'authority' referenced in the February 2020 edits of the Wikipedia entry about the mortality rates of the Spanish Flu (changing them from 10%-20% to 1%-3%), thus, promoting the narrative that COVID-19 is as deadly as the Spanish Flu

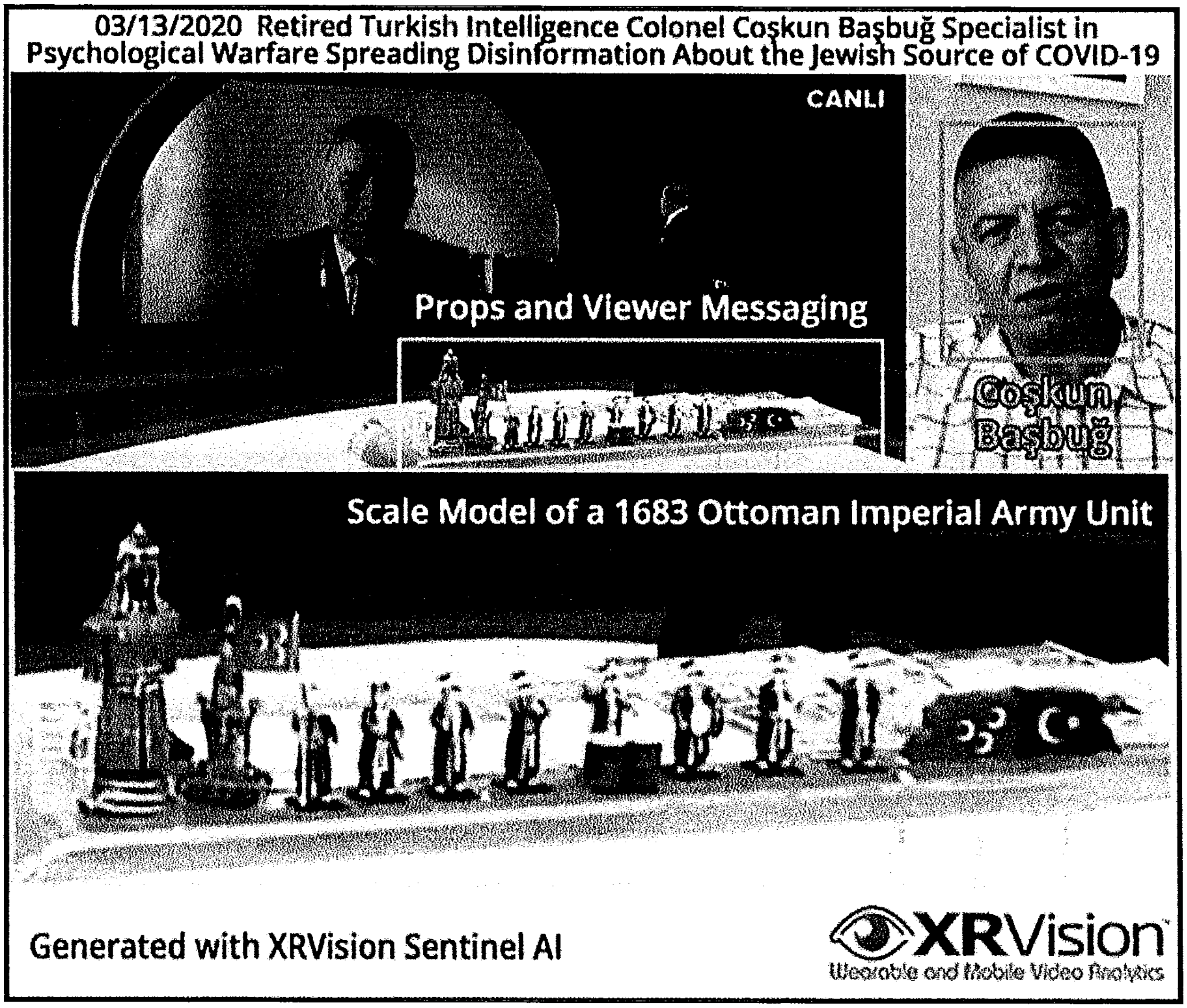
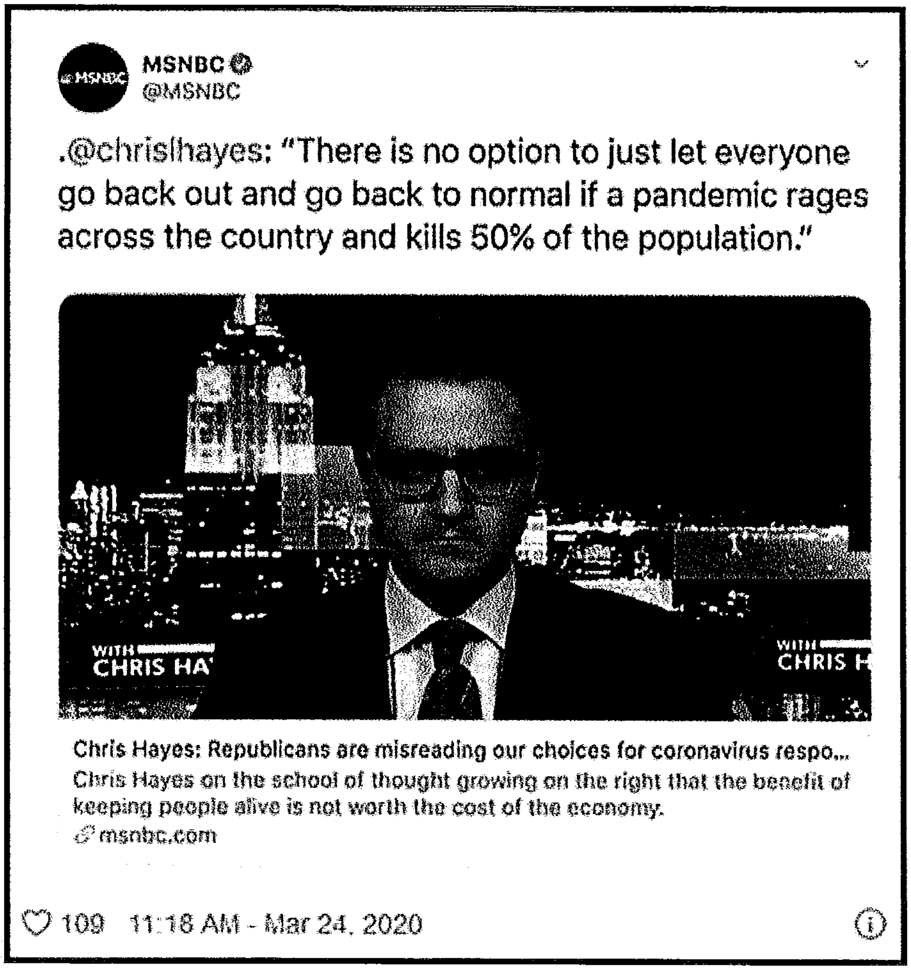

03/13/2020 Retired Turkish Intelligence Colonel Coşkun Başbuğ Specialist in Psychological Warfare Spreading Disinformation About the Jewish Source of COVID-19
CANLI
Props and Viewer Messaging
Coşkun Başbuğ
Scale Model of a 1683 Ottoman Imperial Army Unit
Generated with XRVision Sentinel AI
XRVision
Wearable and Mobile Video Analytics

Image 10: Coşkun Başbuğ, Retired Turkish intelligence Colonel specialist in psychological warfare in an interview on Turkish TV: "*of course, Jews are behind this…*"

***** [Update 03/24/2020] *****

I've received several requests for a proof that MSM outlets have coordinated the above mentioned 'massaging topics' well in advance. For example, that they would predict false astronomical death rates. The following is a posting by Chris Hayes, a lead reporter with MSNBC that predicts a 50% mortality rate.



MSNBC
@MSNBC

.@chrislhayes: "There is no option to just let everyone go back out and go back to normal if a pandemic rages across the country and kills 50% of the population."

Chris Hayes: Republicans are misreading our choices for coronavirus respo...
Chris Hayes on the school of thought growing on the right that the benefit of keeping people alive is not worth the cost of the economy.
msnbc.com

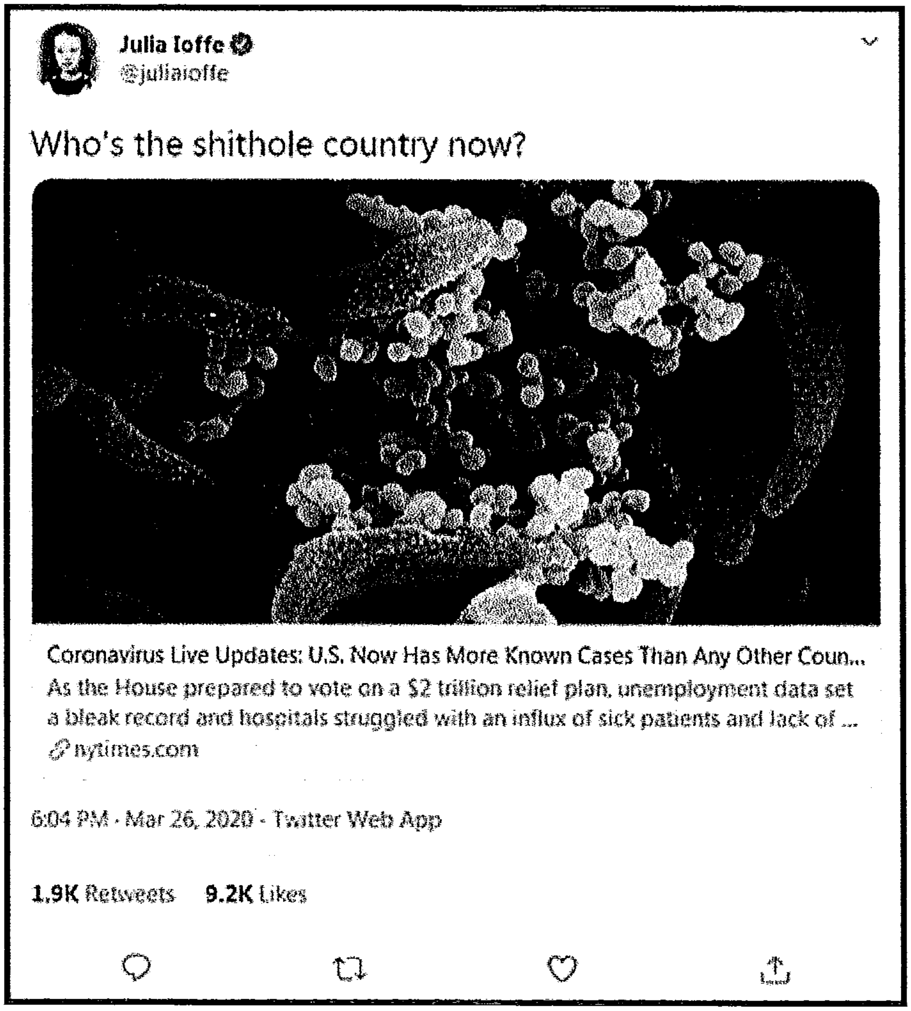
♡ 109 11:18 AM - Mar 24, 2020

***** [Update 03/25/2020] *****

'CBS This Morning' video footage substitution fake. Using imagery from an "ER Ward" in a hospital in Bergamo Lombardy in Northern Italy and passing it as footage an ER in a New York city hospital in order to enhance the fear messaging and attacks on the Trump administration. CBS senior editorial instructions were to 'strip the Sky News watermarks from the footage' so as not to expose its foreign source. The Sky News piece itself is also full of false claims like that the COVID-19 mortality rate is 50%.

***** [Update 03/26/2020] *****

America is a failed state (another item in the above mentioned massaging topics). The following is a sample posting by Julia Ioffe, a GQ Magazine reporter who posted a piece titled "*Who's the shithole country now?*".



Julia Ioffe
@juliaioffe

Who's the shithole country now?

Coronavirus Live Updates: U.S. Now Has More Known Cases Than Any Other Coun...
As the House prepared to vote on a $2 trillion relief plan, unemployment data set a bleak record and hospitals struggled with an influx of sick patients and lack of ...
nytimes.com

6:04 PM · Mar 26, 2020 · Twitter Web App

1.9K Retweets **9.2K** Likes

References and Sourcing

XRVision Sentinel AI Platform – Face recognition, image reconstruction, and object classification

The Effects of Dams on Malaria Transmission in Tigray Region, Northern Ethiopia, and Appropriate Control Measures – Tedros Adhanom Ghebreyesus, University of Nottingham, 2000

Samples of massaging topics showing up in media coverage

Racist Attitudes Could Aid & Abet the Spread of the Pandemic: Laurie Garrett on

Coronavirus

New Evidence of Trump's Botched Response to Coronavirus: Democracy Now

Coronavirus cases could swamp South Dakota hospitals if projections hold: USA Today

Wikipedia Edits Showing an Alignment of the Spanish Flu with the COVID-19 mortality rates

Pre-February 22, 2020 Wikipedia Spanish flu article, the "Around the globe" section stats:

The global mortality rate from the 1918–1919 pandemic is not known, but an estimated 10% to 20% of those who were infected died (case-fatality ratio)."

Post-February 22, 2020 Wikipedia Spanish flu article, the "Around the globe" section stats:

"Estimates vary as to the total number who died. An estimate from 1991 says it killed 25–39 million people.[47] A 2005 estimate put the death toll at probably 50 million (less than 3% of the global population)…"

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https://americascivilwarrising.org/when-tedros-moves-his-lips-beijing-speaks/

EVENT201
A GLOBAL PANDEMIC EXERCISE

Segment 4
Communications Discussion and Epilogue Video

Antes del COVID Bill Gates planeó la censura en redes sociales sobre vacunas junto con peces gordos de la industria farmacéutica, los CDC, medios de comunicación, China y la CIA

13 de marzo de 2021

En octubre de 2019, poco antes del brote de COVID, Gates y otras personas poderosas comenzaron a planificar cómo censurar a los defensores de la seguridad de las vacunas en las redes sociales durante una simulación de sobremesa de una pandemia mundial, conocida como el Evento 201.

Publicidad

Por Robert F. Kennedy, Jr.

Una camarilla de individuos poderosos comenzó a planificar el desalojo masivo de los escépticos de las vacunas de las redes sociales en octubre de 2019, una o dos semanas antes de que el COVID comenzara a circular. Ese mes, el fundador de Microsoft, Bill Gates, organizó un ejercicio de cuatro simulaciones «de mesa» de una pandemia mundial de coronavirus con otros personajes de alto rango. El ejercicio se denominó Evento 201.

Los co-conspiradores de Gates incluyeron representantes del Banco Mundial, el Foro Económico Mundial, el Centro de Población de la Universidad Bloomberg/Johns Hopkins, los Centros para el Control y la Prevención de Enfermedades, varias potencias de los medios de comunicación, el gobierno chino, una antigua Agencia Central de Inteligencia/Director de la Agencia de Seguridad Nacional (no existe tal cosa como un ex oficial de la CIA), fabricante de vacunas Johnson & Johnson, las industrias de finanzas, bioseguridad y Edelman, la firma de relaciones públicas corporativas líder en el mundo.

Publicidad

Bajo la dirección de Gates, estas eminencias interpretaron el papel de miembros de un Consejo de Control de la Pandemia, desarrollando estrategias gubernamentales para controlar la pandemia, la narrativa y la población. No hace falta decir que se habló poco sobre la construcción de sistemas inmunológicos, remedios listos para usar o medicamentos y vitaminas terapéuticos sin patente, pero se habló mucho sobre la promoción de la adopción de nuevos medicamentos y vacunas antivirales patentables .

Los participantes se centraron principalmente en la planificación de estrategias estatales policiales centradas en la industria y que fomentan el miedo para gestionar un contagio global imaginario de coronavirus que culmina en una censura masiva de las redes sociales.

Curiosamente, Gates ahora afirma que la simulación no ocurrió. El 12 de abril de 2020, Gates le dijo a la BBC: "Ahora aquí estamos. No simulamos esto, no practicamos, por lo que tanto las políticas de salud como las políticas económicas, nos encontramos en un territorio inexplorado".
Desafortunadamente para Gates, los videos del evento todavía están disponibles en Internet. En ellos se muestra que Gates y su equipo sí simularon políticas económicas y de salud. Es difícil tragar lo que Gates ha olvidado.
La epidemia de COVID simulada del Evento 201 de Gates causó 65 millones de muertes en el punto final de 18 meses y un colapso económico global que duró hasta una década. En comparación con la simulación de Gates, por lo tanto, la actual crisis del COVID-19 es un poco fallida, ya que ha impuesto solo 2,5 millones de muertes dudosamente «atribuidas al COVID» en los últimos 13 meses.

Publicidad

Las muertes "atribuidas a COVID" en la situación de la vida real son muy cuestionables y deben considerarse en el contexto de una población mundial de 7.800 millones, con cerca de 59 millones de muertes esperadas anualmente. Las predicciones de un colapso económico de una década probablemente resulten más precisas, pero solo debido al bloqueo draconiano promovido por Gates.

El guión del Evento 201 de Gates imagina grandes disturbios contra las vacunas provocados por publicaciones en Internet. La presunción universal y resuelta entre sus participantes fue que tal crisis resultaría una oportunidad conveniente para promover nuevas vacunas y reforzar los controles mediante un estado de vigilancia y censura.

A continuación verán un resumen del segmento cuatro del guion, sobre manipulación y control de la opinión pública, que es muy revelador. Sorprendentemente, predijo la crisis actual de la democracia:

- Los participantes discutieron los mecanismos para controlar la "desinformación", al "inundar" los medios de comunicación con propaganda ("buena información"), imponer sanciones por difundir falsedades y desacreditar el movimiento antivacunas.
- Jane Halton, del ANZ Bank de Australia, una de las autoras de la opresiva política de Australia «no jab, no pay», aseguró a los participantes que la Fundación Gates está creando algoritmos «para filtrar información en estas plataformas de redes sociales» para proteger al público de peligros pensamientos e información.

- A George Gao, el director profético del Centro Chino para el Control de Enfermedades, le preocupa cómo suprimir los «rumores» de que el virus se genera en el laboratorio: «La gente cree, 'Esto es artificial' ... [y que] alguna compañía farmacéutica creó el virus»
- Chen Huang, un científico investigador de Apple, académico de Google y el principal experto mundial en rastreo y tecnología de reconocimiento facial, interpreta al presentador de noticias que informa sobre las contramedidas del gobierno. Él culpa de los disturbios a los activistas contra las vacunas y predice que Twitter y Facebook cooperarán para «identificar [e] y eliminar [e] un número preocupante de cuentas dedicadas a difundir información errónea sobre el brote» y para implementar «cierres de Internet ... para sofocar el pánico»
- A la Dra. Tara Kirk Sell, investigadora principal del Centro Johns Hopkins para la Seguridad de la Salud de la Escuela de Salud Bloomberg, le preocupa que las empresas farmacéuticas estén siendo acusadas de introducir el virus para poder ganar dinero con medicamentos y vacunas: "[Hemos] visto que la fe pública en sus productos caen en picado «. Ella observa con alarma que "los disturbios, debido a rumores falsos y mensajes divisivos, están aumentando y están exacerbando la propagación de la enfermedad a medida que los niveles de confianza disminuyen y la gente deja de cooperar con los esfuerzos de respuesta. Este es un problema enorme, que amenaza a los gobiernos y las instituciones confiables».

Sell les recuerda a sus compañeros colaboradores que «sabemos que las redes sociales son ahora la principal forma en que muchas personas reciben sus noticias, por lo que las interrupciones en estas plataformas podrían frenar la difusión de información errónea». Hay muchas formas, aconseja Sell, para que los aliados gubernamentales y de la industria logren este objetivo: "Algunos gobiernos han tomado el control del acceso nacional a Internet. Otros están censurando sitios web y contenido de redes sociales y un pequeño número ha cerrado el acceso a Internet por completo para evitar la propagación de información errónea. Se han impuesto sanciones por difundir falsedades dañinas, incluidas las detenciones «.

[illegible]

- Matthew Harrington, director ejecutivo de Edelman Public Relations, está de acuerdo en que las redes sociales deben estar alineadas para promover la política del gobierno: "También creo que estamos en un momento en el que las plataformas de redes sociales deben dar un paso adelante y reconocer el momento para afirmar que son una plataforma tecnológica y no una emisora. De hecho, tienen que participar en la transmisión de información precisa y asociarse con las comunidades científicas y de salud para contrapesar, si no inundar la zona, de información precisa. Porque tratar de volver a meter al genio en la botella de desinformación no es posible ".
- Stephen Redd, el almirante del Servicio de Salud Pública, tiene la siniestra noción de que el gobierno debería extraer datos de las redes sociales para identificar a las personas con creencias negativas: "Creo que con las plataformas de las redes sociales, existe la oportunidad de comprender quiénes son susceptibles ... a desinformación, por

lo que creo que existe la oportunidad de recopilar datos de ese mecanismo de comunicación «.

- Adrian Thomas de Johnson & Johnson recomienda una estrategia para abordar los problemas de estas empresas cuando «en realidad se estaban extendiendo rumores» de que sus productos mal probados «están causando muertes y, por lo tanto, los pacientes ya no los toman». Sugiere: «Tal vez estemos cometiendo el error de informar y contar todas las muertes e infecciones».
- La ex subdirectora de la CIA, Avril Haines dio a conocer una estrategia para «inundar la zona» con propaganda de «fuentes confiables», incluidos «líderes comunitarios influyentes, así como trabajadores de la salud». Advierte sobre «la información falsa que está empezando a obstaculizar nuestra capacidad para abordar la pandemia, entonces debemos ser capaces de responder rápidamente».
- Matthew Harrington (director ejecutivo de Edelman) observa que Internet, que una vez prometió la descentralización y democratización de la información, ahora debe centralizarse: "Creo que basarnos un poco en lo que dijo Avril, creo que en conversaciones anteriores en las que ' Hemos hablado de la centralización en torno a la gestión de la información o las necesidades de salud pública, es necesario que haya una respuesta centralizada en torno al enfoque de las comunicaciones que luego se transmita en cascada a los defensores informados, representados en las comunidades de ONG, los profesionales médicos, etc. «
- Tom Inglesby (asesor experto en bioseguridad de John Hopkins para los Institutos Nacionales de Salud, el Pentágono y Seguridad Nacional) está de acuerdo en que se necesita un control centralizado: «¿Te refieres a internacional centralizado?»
- Matthew Harrington (Edelman) responde que el acceso a la información debería ser: «Centralizado a nivel internacional, porque creo que debe haber un depósito central de datos y mensajes clave».
- Hasti Taghi (Asesor de medios) resume: "El movimiento contra las vacunas fue muy fuerte y esto es algo específicamente a través de las redes sociales que se ha extendido. Entonces, a medida que hacemos la investigación para encontrar las vacunas adecuadas para ayudar a prevenir la continuación de esto, ¿cómo podemos obtener la información correcta? ¿Cómo comunicamos la información correcta para garantizar que el público confíe en estas vacunas que estamos creando? «
- Kevin McAleese, oficial de comunicaciones de proyectos agrícolas financiados por Gates, observa que: "Para mí, está claro que los países deben hacer grandes esfuerzos para gestionar tanto la desinformación como la desinformación. Sabemos que las empresas de redes sociales están trabajando las veinticuatro horas del día para combatir estas campañas de desinformación. La tarea de identificar a todos los malos actores es inmensa. Este es un gran problema que nos impedirá poner fin a la pandemia e incluso podría conducir a la caída de gobiernos, como vimos en la Primavera Árabe. Si la solución significa controlar y reducir el acceso a la información, creo que es la elección correcta».

- Tom Inglesby, director del Johns Hopkins Center for Health Security de Bloomberg, está de acuerdo y pregunta si «En este caso, ¿cree que los gobiernos están en el punto en el que necesitan exigir que las empresas de redes sociales operen de cierta manera?»
- Lavan Thiru, ministro de Finanzas de Singapur, sugiere que el gobierno podría dar ejemplos de disidentes con "acciones gubernamentales o de ejecución contra noticias falsas. Algunos de nosotros, estas nuevas regulaciones se han implementado sobre cómo manejamos las noticias falsas. Tal vez este sea un momento para que mostremos algunos casos en los que podamos presentar a algunos malos actores y dejar que los tribunales decidan si realmente han difundido algunas noticias falsas».

Esto es un gran ejemplo de cómo Gates y su aparato gubernamental, farmacéutico y de inteligencia telegrafiaron sus planes para censurar y controlar a los medios durante la pandemia antes de que sucediera. En otra extraña coincidencia, el COVID-19 comenzó a circular entre las poblaciones globales a los pocos días de esta reunión.

🔎 | Transcripción Sección 4 Evento 201 | Sección 4 Evento 201 – Youtube | TheDefender

https://trikooba.com/2021/03/13/antes-del-covid-bill-gates-planeo-la-censura-en-redes-sociales-sobre-vacunas-junto-con-peces-gordos-de-la-industria-farmaceutica-los-cdc-medios-de-comunicacion-china-y-la-cia/

US 20200279585A1

(19) United States

(12) Patent Application Publication

Rothschild

(10) **Pub. No.: US 2020/0279585 A1**

(43) **Pub. Date: Sep. 3, 2020**

(54) **SYSTEM AND METHOD FOR TESTING FOR COVID-19**

(71) Applicant: **Richard A. Rothschild**, London (GB)

(72) Inventor: **Richard A. Rothschild**, London (GB)

(21) Appl. No.: **16/876,114**

(22) Filed: **May 17, 2020**

Related U.S. Application Data

(63) Continuation-in-part of application No. 16/704,844, filed on Dec. 5, 2019, which is a continuation of application No. 16/273,141, filed on Feb. 11, 2019, now Pat. No. 10,522,188, which is a continuation of application No. 15/495,485, filed on Apr. 24, 2017, now Pat. No. 10,242,713, which is a continuation of application No. 15/293,211, filed on Oct. 13, 2016, now abandoned.

(60) Provisional application No. 62/240,783, filed on Oct. 13, 2015.

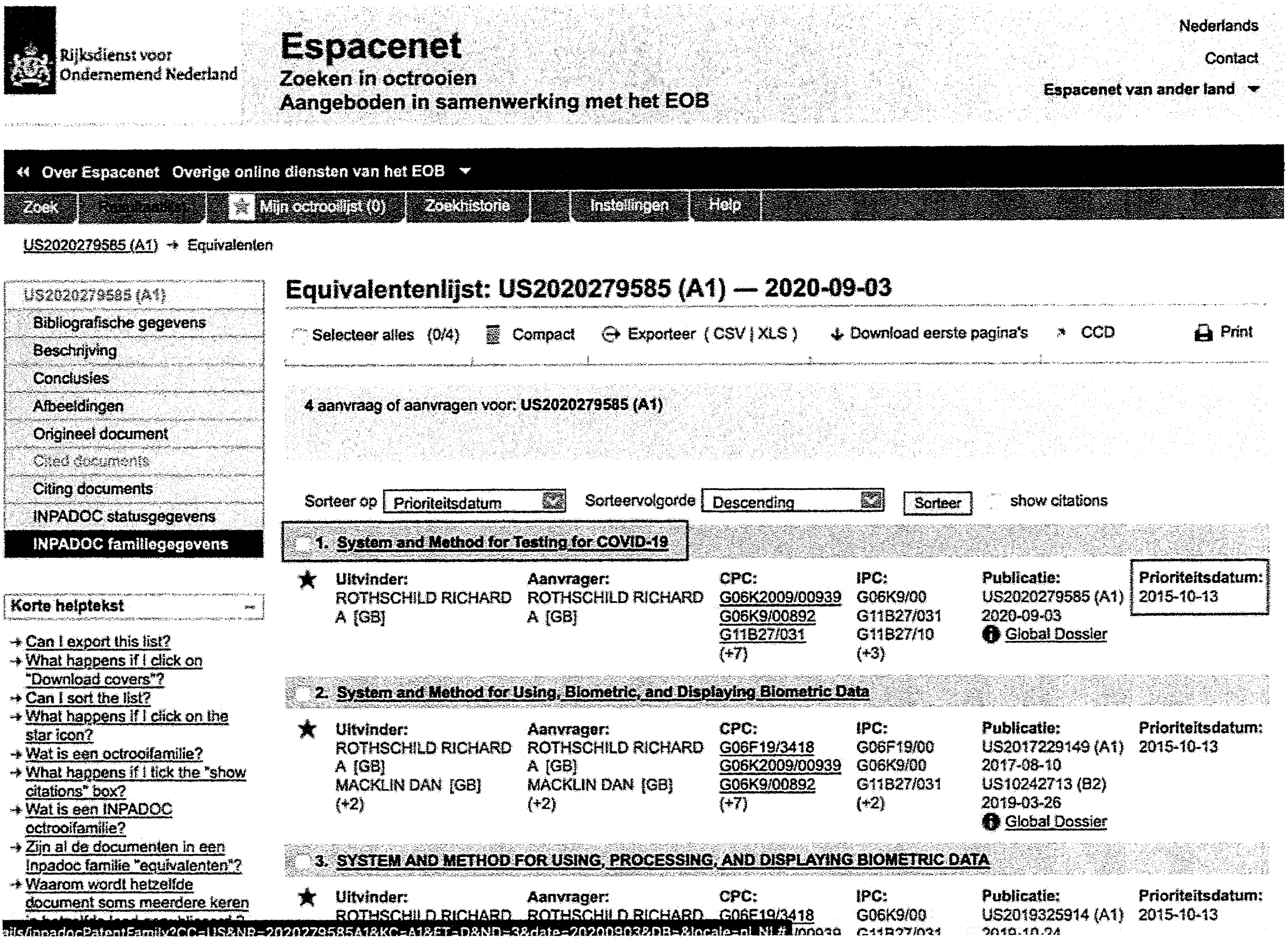
G06K 9/00	(2006.01)
H04N 5/76	(2006.01)
H04N 9/82	(2006.01)
G16H 40/63	(2006.01)

(52) **U.S. Cl.**

CPC ***G11B 27/10*** (2013.01); ***G11B 27/031*** (2013.01); ***G06K 9/00892*** (2013.01); ***G06K 2009/00939*** (2013.01); ***H04N 9/8205*** (2013.01); ***G11B 27/102*** (2013.01); ***G16H 40/63*** (2018.01); ***H04N 5/76*** (2013.01)

(57) **ABSTRACT**

A method is provided for acquiring and transmitting biometric data (e.g., vital signs) of a user, where the data is analyzed to determine whether the user is suffering from a viral infection, such as COVID-19. The method includes using a pulse oximeter to acquire at least pulse and blood oxygen saturation percentage, which is transmitted wirelessly to a smartphone. To ensure that the data is accurate, an accelerometer within the smartphone is used to measure movement of the smartphone and/or the user. Once accurate data is acquired, it is uploaded to the cloud (or host), where the data is used (alone or together with other vital signs) to



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1. System and Method for Testing for COVID-19

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ROTHSCHILD RICHARD A [GB]	ROTHSCHILD RICHARD A [GB]	G06K2009/00939 G06K9/00892 G11B27/031 (+7)	G06K9/00 G11B27/031 G11B27/10 (+3)	US2020279585 (A1) 2020-09-03 Global Dossier	2015-10-13

2. System and Method for Using, Biometric, and Displaying Biometric Data

Uitvinder:	Aanvrager:	CPC:	IPC:	Publicatie:	Prioriteitsdatum:
ROTHSCHILD RICHARD A [GB] MACKLIN DAN [GB] (+2)	ROTHSCHILD RICHARD A [GB] MACKLIN DAN [GB] (+2)	G06F19/3418 G06K2009/00939 G06K9/00892 (+7)	G06F19/00 G06K9/00 G11B27/031 (+2)	US2017229149 (A1) 2017-08-10 US10242713 (B2) 2019-03-26 Global Dossier	2015-10-13

3. SYSTEM AND METHOD FOR USING, PROCESSING, AND DISPLAYING BIOMETRIC DATA

Uitvinder:	Aanvrager:	CPC:	IPC:	Publicatie:	Prioriteitsdatum:
ROTHSCHILD RICHARD	ROTHSCHILD RICHARD	G06F19/3418	G06K9/00	US2019325914 (A1)	2015-10-13

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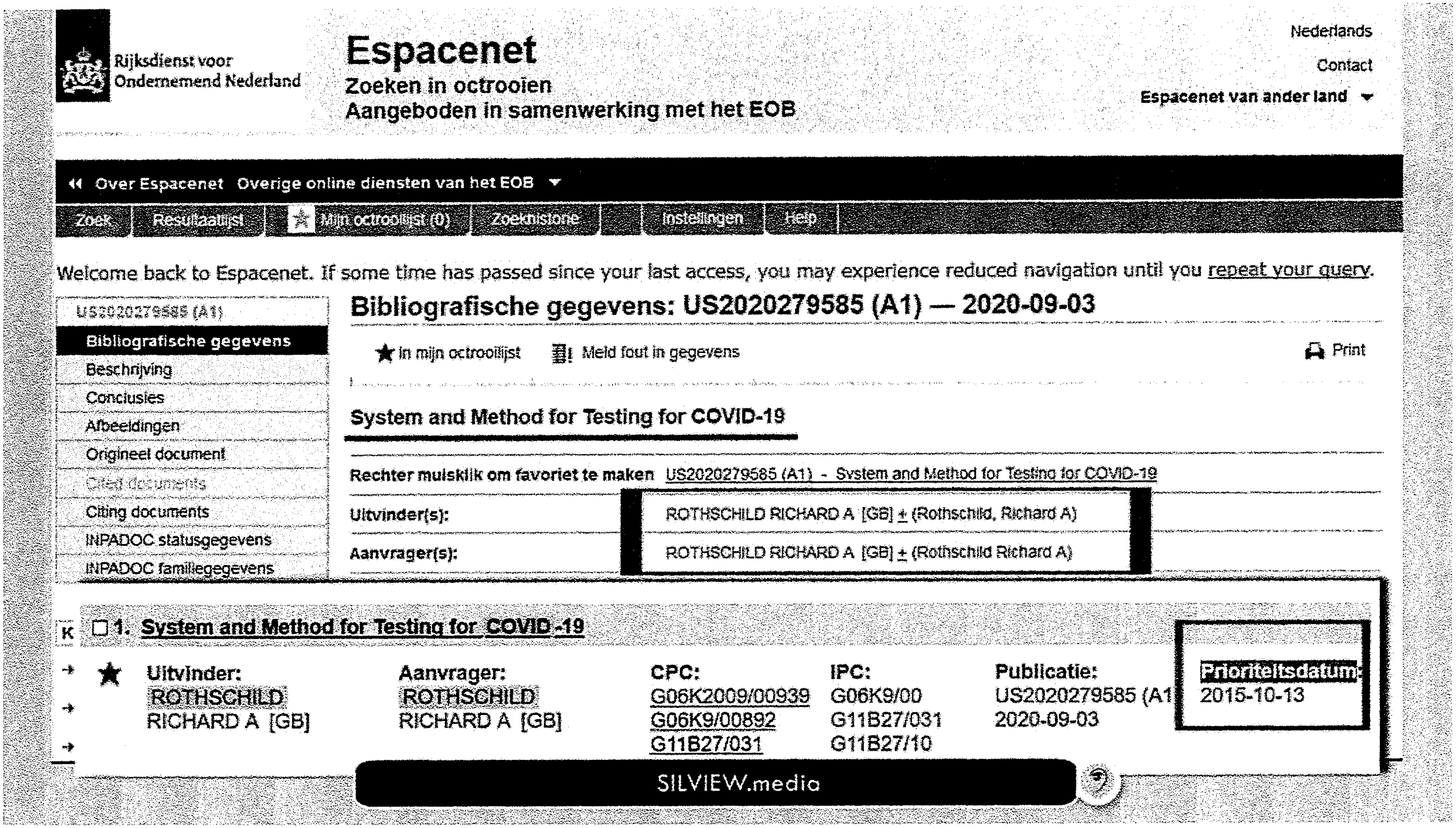

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Bibliografische gegevens: US2020279585 (A1) — 2020-09-03

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System and Method for Testing for COVID-19

Rechter muisklik om favoriet te maken US2020279585 (A1) - System and Method for Testing for COVID-19

Uitvinder(s): ROTHSCHILD RICHARD A [GB] + (Rothschild, Richard A)

Aanvrager(s): ROTHSCHILD RICHARD A [GB] + (Rothschild Richard A)

☐ 1. System and Method for Testing for COVID-19

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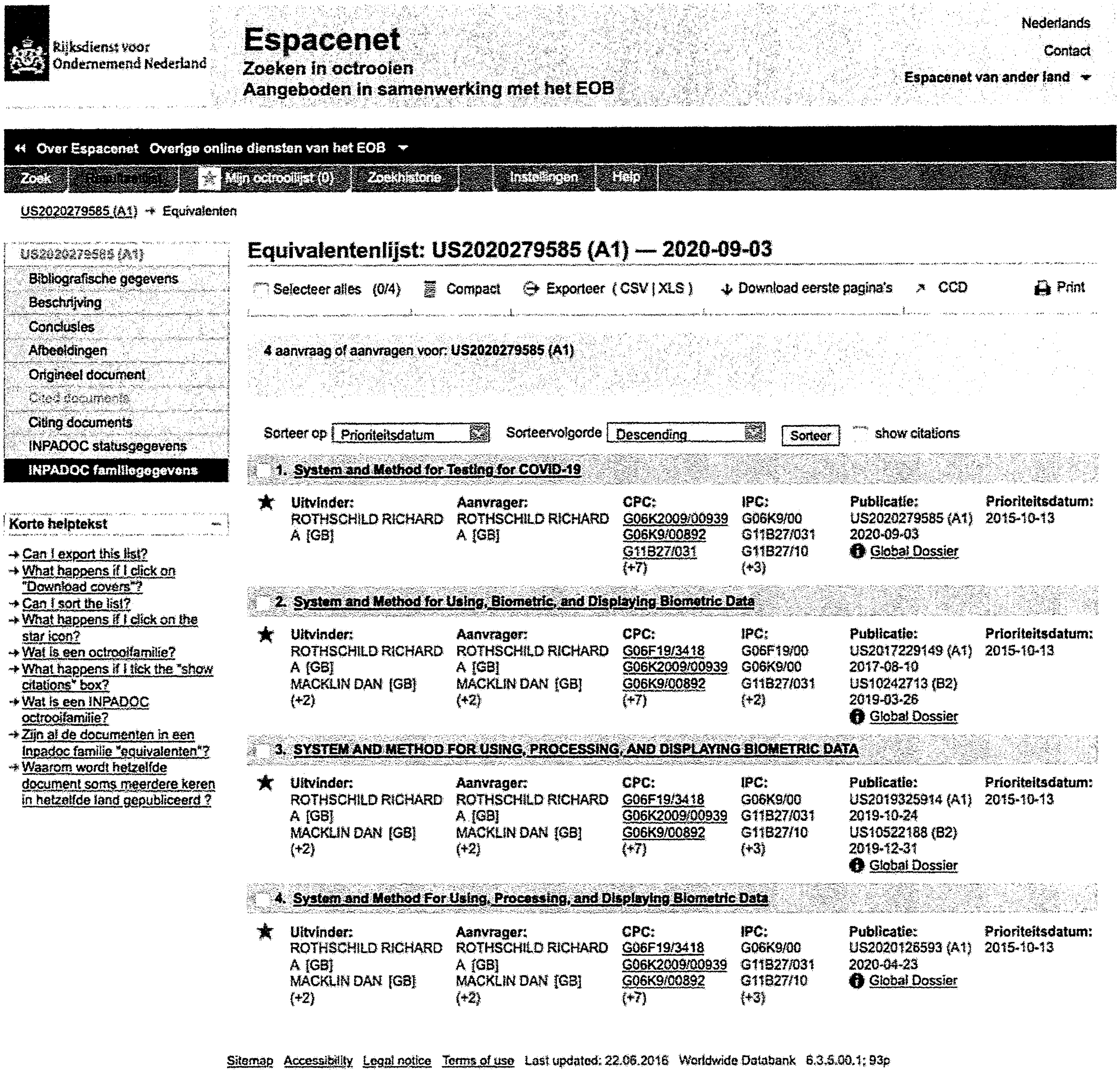

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☐ 3. SYSTEM AND METHOD FOR USING, PROCESSING, AND DISPLAYING BIOMETRIC DATA

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☐ 4. System and Method For Using, Processing, and Displaying Biometric Data

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Atomic Bombshell: We Have Proof That Rothschilds Patented Covid-19 Biometric Tests in 2015 and 2017.

by JayTeOctober 20, 20207.4kViews 15Votes 8Comments

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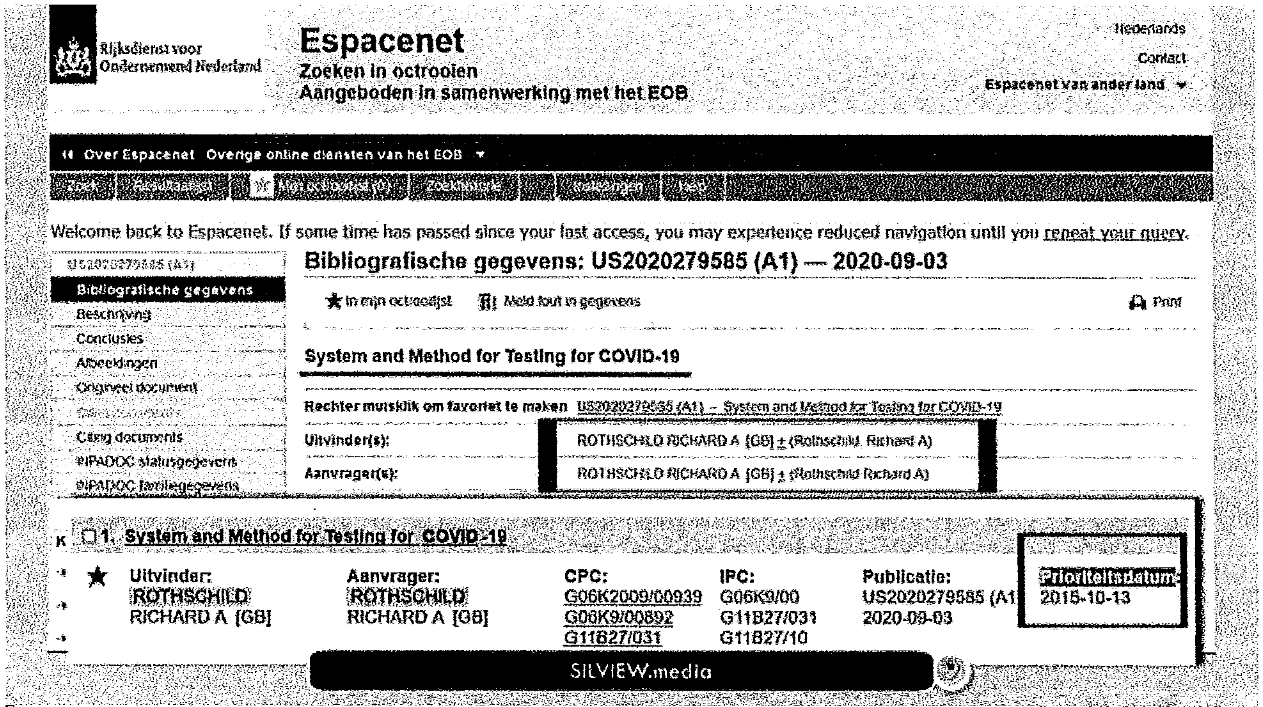

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System and Method for Testing for COVID-19

Rechter muisklik om favoriet te maken US2020279585 (A1) - System and Method for Testing for COVID-19

Uitvinder(s): ROTHSCHILD RICHARD A [GB] + (Rothschild, Richard A)

Aanvrager(s): ROTHSCHILD RICHARD A [GB] + (Rothschild Richard A)

☐ 1. System and Method for Testing for COVID-19

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by Silviu "Silview" Costinescu

It's not disputable, since the information comes from official patent registries in the Netherlands and US. And we have all the documentation.

As we've shown in previous exposes, the whole Covidiocracy is a masquerade and a simulation long prepared by The World Bank / IMF / The Rothschilds / World Economic Forum (basically the world's "elite", the 0.1%) and their lemmings, with Rockefeller partnership.

Our newest discoveries further these previous revelations.

First Registration: Netherlands, Oct. 13, 2015

Source: Dutch Government patent registry website / **First filled in 2015:** Source link
Proof that the patent was filed back in 2015 (source link here):

A method is provided for acquiring and transmitting biometric data (e.g., vital signs) of a user, where the data is analyzed to determine whether the user is suffering from a viral infection, such as COVID-19.

The method includes using a pulse oximeter to acquire at least pulse and blood oxygen saturation percentage, which is transmitted wirelessly to a smartphone.

To ensure that the data is accurate, an accelerometer within the smartphone is used to measure movement of the smartphone and/or the user.

Once accurate data is acquired, it is uploaded to the cloud (or host), where the data is used (alone or together with other vital signs) to determine whether the user is suffering from (or likely to suffer from) a viral infection, such as COVID-19.

Depending on the specific requirements, the data, changes thereto, and/or the determination can be used to alert medical staff and take corresponding actions.

Second Registration: USA, Oct. 13, 2015

DOWNLOAD FROM GOOGLE PATENTS (PDF)

Detailed info below.

ONE KEY DETAIL STRUCK ME ON THESE REGISTRATIONS: Both were filed and updated years ago, but they were SCHEDULED to be made public in September 2020. This is sufficient evidence that they knew in 2015 what's going to happen in September 2020!

So how did Mr. Richard A. Rothschild know to create a system and method for testing for a disease that didn't exist, and know exactly how the disease will be called, including the year in which the disease will be discovered?

Another Bombshell Fact: Millions Of COVID-19 Test Kits Have Been Sold In 2017 And 2018

Data from the World Integrated Trade Solution, however, shows something astonishing:

"in 2017 and 2018 – two years before COVID-19 – hundreds of millions of test kits for COVID-19 were distributed worldwide."

Two years before the outbreak of COVID-19 the USA, the EU, China and nations around the world started exporting millions of diagnostic test instruments for… COVID-19, a disease that supposedly didn't even exist back then.

None of the above makes sense, unless this is not actually a pandemic, but a PLANdemic. And I think the following article proves just that: Ultimate Proof: Covid-19 Was Planned to Usher in the New World Order.

https://humansarefree.com/2020/09/proof-covid-19-planned-new-world-order.html

https://theduran.com/atomic-bombshell-we-have-proof-that-rothschilds-patented-covid-19-biometric-tests-in-2015-and-2017/

World Health Organization

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Partnering for a healthier world

WHO is only able to protect health, humanity's most precious resource, because of the generosity and collaboration of our Member States, the private sector, foundations, academic institutions, civil society and other partners.

WHO strives to be a good partner in global health by showing the results of our work - people's health improving, unnecessary death from diseases reduced, and overall quality of life elevated for people everywhere. That's why WHO launched An Impact Framework to measure the results of our 5-year strategy, the 13th General Programme of Work.

The Organization wants to celebrate the achievements that have been made in global health through strategic investments with our partners. The partner impact sheets demonstrate these results and give an overview of the broader partnership.

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As part of the Financing Campaign WHO aims to highlight key areas of work in global health that would not be possible without our top contributors and top flexible donors. Thank you all for the impact you are making by investing in health.

WHO exhibits financing and achievements with our partners in an open and transparent way through our budget portal.

We count on your continued support for our five-year strategy, the 13th General Programme of Work, which cost US$ 14.14 billion. The next five years will determine if we reach our targets for the Sustainable Development Goals, of which health is an integral part. Together we can realize a healthier, safer and more equitable world in which no-one is left behind.

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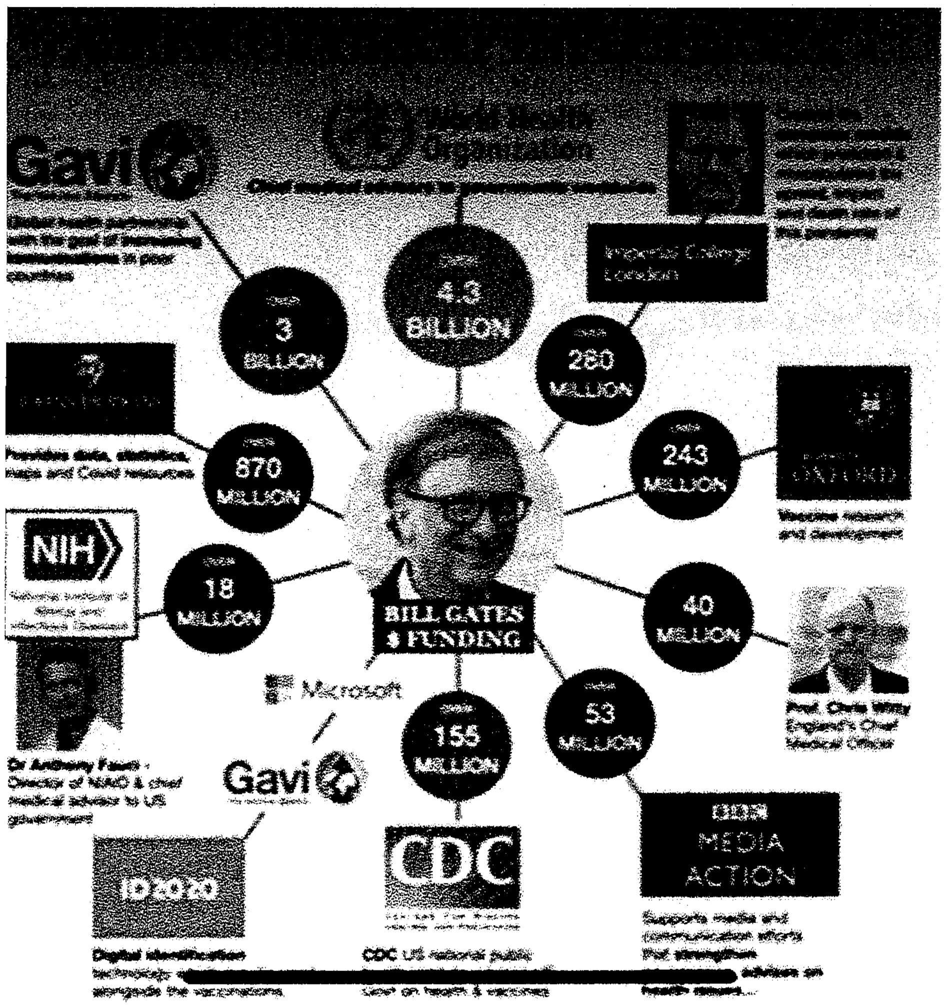
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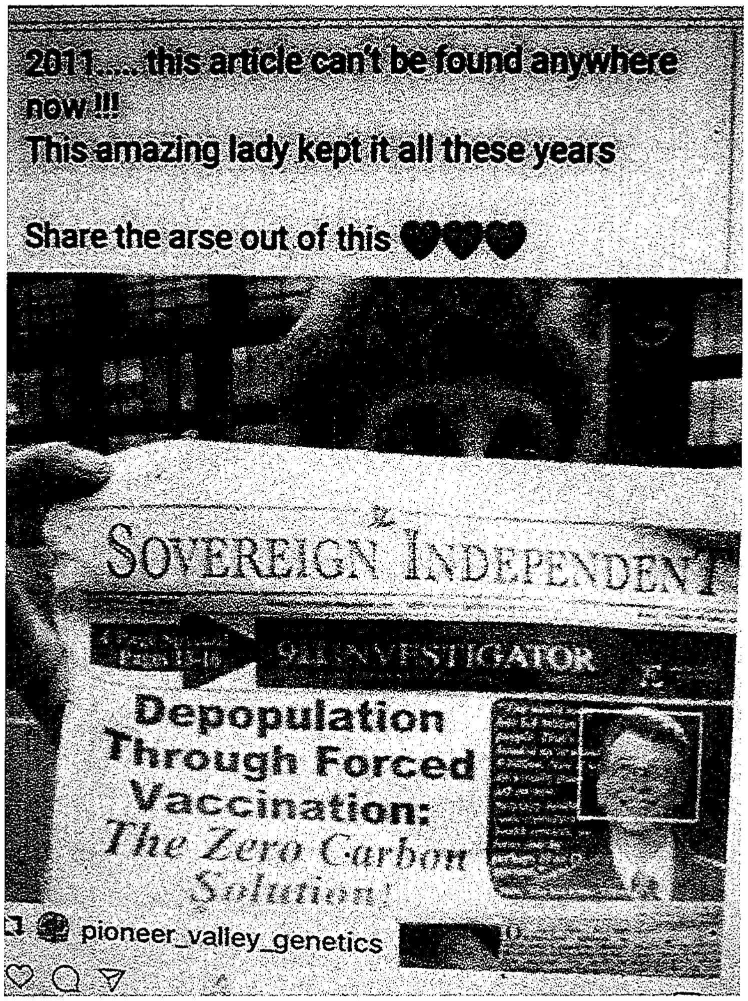

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This amazing lady kept it all these years

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SOVEREIGN INDEPENDENT
911 INVESTIGATOR

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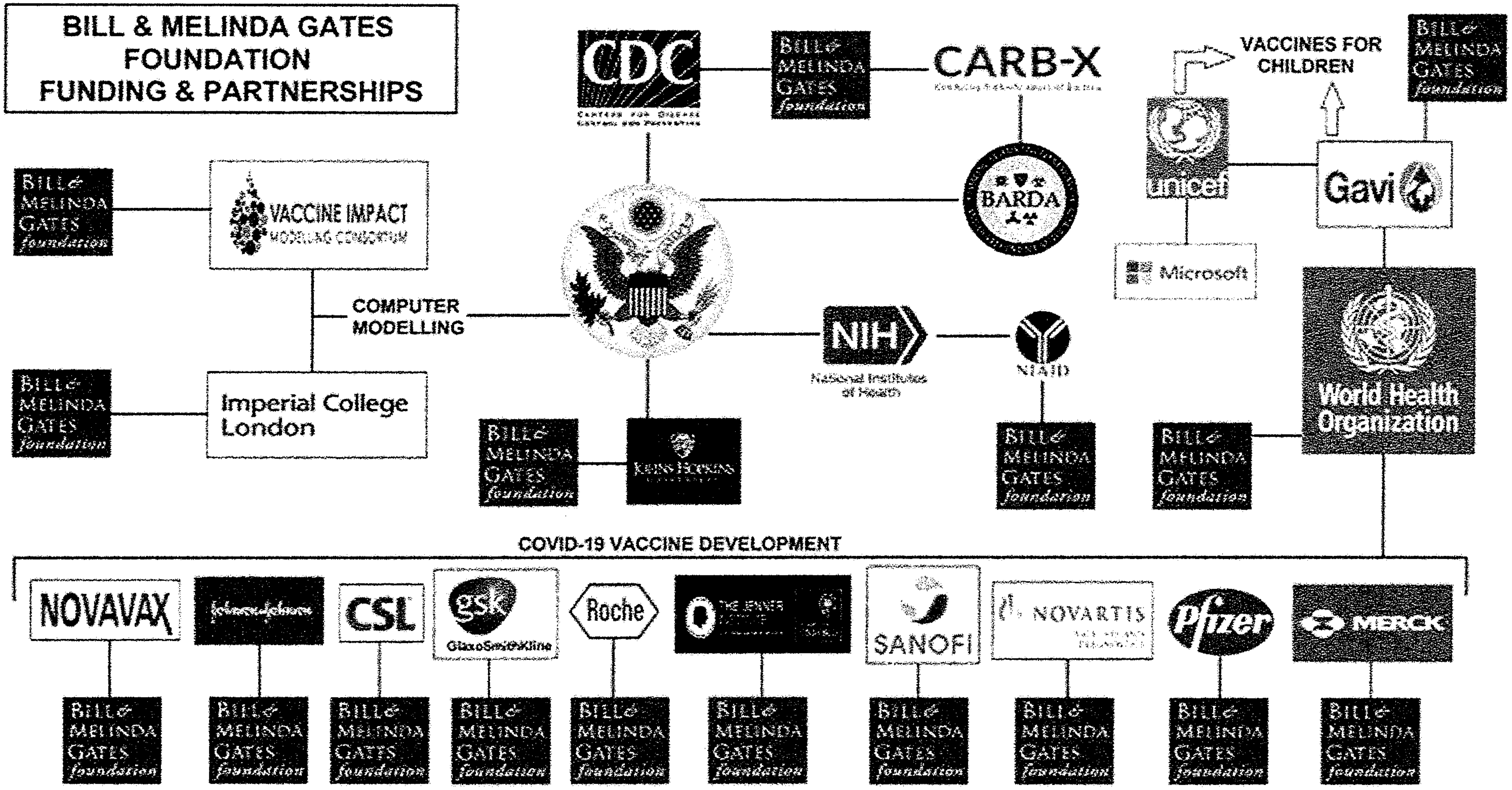
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